

**An Analysis of TRIPS-Plus Protections relating to  
Pharmaceuticals and Geographical Indications in CETA and the  
CPTPP**

**Implications for a European Union – New Zealand Free Trade Agreement**

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A thesis submitted in fulfilment of the requirements for the Degree of

Master of Laws

in the University of Canterbury

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University of Canterbury

2019

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## ACKNOWLEDGEMENTS

I wish to acknowledge those people who have contributed to the completion of this thesis.

To my supervisor, Dr Christian Riffel. Thank you for your guidance throughout this thesis. I appreciate and value your knowledge which you were more than happy to impart.

To the girls at Strandbags, Riccarton. I sincerely appreciate all of your encouragement and support throughout my thesis. Whether it be listening to me thinking aloud, providing me with much-needed banter and hugs, or covering my shifts so I had the time to work on this thesis, I am truly grateful for everything you've done.

To my dear family and friends, I wish to thank you for all your contribution over the years. In particular to my grandparents, for all the beautiful letters and words of encouragement throughout my entire tertiary education. You have no idea how much I cherish your love and thoughtfulness. And to Sally, for putting up with me droning on to you over the years about my study and for always being there for me when I needed it. Even though we don't talk often you've always been just a phone call away. Thank you for everything.

To Rose, I don't know what I would have done without your support these past few months! From proof-reading this thesis to ensuring I was well-fed and taken care of, you've been amazing. Thank you.

To Marcel, I couldn't have done this without your love and unwavering support. Thank you for having the confidence in me and for encouraging me to keep going.

Finally, to my closest family. Dad, you have always encouraged me in everything I have done. You have taught me to take every opportunity that is offered and to strive to do more than what I thought was achievable. I am so grateful for all of your support and the 'can-do' attitude that you have instilled in me. Mum, you have been my absolute rock. I am truly indebted to you for your never-ending love and support. You have pushed me to get back on the horse when I've almost given up and I cannot thank you enough for having faith in me. Claire, thank you for being there for me. I couldn't have asked for a more supportive sister. I love you all so much.

## ABSTRACT

On 29 October 2015, the European Union (EU) and New Zealand announced their intention to commence the process for negotiations to achieve a bilateral Free Trade Agreement (FTA). Closer trade relations would undoubtedly provide immense economic benefits to New Zealand. It would, however, come at a cost in certain areas. One area where concerns have been raised relates to intellectual property (IP) and the increasing trend of including higher levels or ‘TRIPS-plus’ protections in FTAs. This is particularly so in relation to pharmaceuticals and geographical indications, as stronger IP protection in those areas would come at a significant cost to New Zealand. Given the confidential nature of trade negotiations, the extent to which TRIPS-plus protections may be included within an EU-NZ FTA and the implications for New Zealand law remain unknown. This thesis seeks to address this issue.

First, a comparative interpretative analysis of TRIPS-plus protections relating to pharmaceuticals and geographical indications within recent FTAs concluded by each Party shall be conducted to identify those protections which may be included within an EU-NZ FTA. A further analysis shall be conducted to determine the domestic positions of the EU and New Zealand in order to shed light on the context of those FTAs and to identify any common interests or positions regarding IP protection. By succinctly identifying those TRIPS-plus protections which could be included within an EU-NZ FTA, a further discussion on the implications for New Zealand will then ensue. This discussion will seek to address such issues as whether New Zealand *should* implement TRIPS-plus protections and, if so, to what extent.

## **LIST OF ABBREVIATIONS**

CETA	Comprehensive Economic and Trade Agreement
CPTPP	Comprehensive and Progressive Agreement for Trans-Pacific Partnership
EPC	European Patent Convention
EPO	European Patent Office
EU	European Union
FTA	Free Trade Agreement
GATT	General Agreement on Tariffs and Trade
GI	Geographical Indication
IP	Intellectual Property
IPONZ	Intellectual Property Office of New Zealand
IPR	Intellectual Property Right
MFAT	Ministry of Foreign Affairs and Trade
MFN	Most-Favoured Nation
NZ	New Zealand
PDO	Protected Designation of Origin
PGI	Protected Geographical Indication
SPC	Supplementary Protection Certificate
TFEU	Treaty on the Functioning of the European Union
TPP	Trans-Pacific Partnership
TRIPS	Agreement on Trade-Related Aspects of Intellectual Property Rights
UPC	Unitary Patent Convention
UK	United Kingdom
US	United States of America
VCLT	Vienna Convention on the Law of Treaties
WTO	World Trade Organisation



## *I Introduction*

### *A General Background*

On 29 October 2015, the European Union (EU) and New Zealand announced their intention to commence the process for negotiations to achieve a bilateral Free Trade Agreement (FTA).<sup>1</sup> Recognising the EU as New Zealand's third-largest trading partner,<sup>2</sup> closer trade relations would open opportunities to enhance economic growth and investment while strengthening the longstanding relationship between the two parties. While an FTA would undoubtedly provide immense economic benefits to New Zealand, it would, however, come at a cost in certain areas.

One area where concerns have been raised relates to intellectual property rights (IPRs). New Zealand provides the minimum intellectual property (IP) standards, consistent with its international obligations under the Agreement on Trade-Related Aspects of Intellectual Property Rights (TRIPS Agreement).<sup>3</sup> The EU, however, is a proponent of enhanced IP or so-called 'TRIPS-plus' protection, imposing stronger protection within both its domestic laws and its trade agreements with third parties. In order to gain concessions in sensitive areas such as agriculture, New Zealand will likely be required to implement some form of TRIPS-plus protection.

Of particular interest to this research paper are TRIPS-plus protections relating to pharmaceuticals and geographical indications (GIs). As a country heavily reliant on imported and subsidised pharmaceutical products, the implementation of stronger IP protection may have the effect of increasing legal barriers to a consumers' ability to access affordable medicines, thereby benefiting pharmaceutical companies at the expense of the New Zealand citizen. Whereas the registration of terms under a geographical indication (GI) may prevent a New Zealand producer from using that term in the labelling and marketing of their product, resulting in the forced adaptation of well-established business practices which have been

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<sup>1</sup> European Commission "Statement of the Presidents of the European Council and the European Commission and the New Zealand Prime Minister" (press release, 29 October 2015).

<sup>2</sup> Ministry of Foreign Affairs and Trade "Key facts on EU-NZ Trade" <<https://www.mfat.govt.nz/en/trade/free-trade-agreements/agreements-under-negotiation/eu-fta/key-facts-on-nz-eu-trade/>>.

<sup>3</sup> Agreement on Trade-Related Aspects of Intellectual Property Rights (Marrakesh, Morocco, 15 April 1994), Marrakesh Agreement Establishing the World Trade Organisation, Annex 1C, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 321 (1999), 1869 U.N.T.S. 299, 33 I.L.M. 1197 (1994) [hereinafter TRIPS Agreement].

permissible for many years. This may similarly increase legal barriers to a consumers' ability to access similar products as it reduces competition for a product labelled under what may have been a well-known term.

Presently, it remains uncertain what level and scope of protection for pharmaceuticals and GIs may be included within an EU-NZ FTA. Given the position of the EU, it may be inferred that the inclusion of TRIPS-plus protections will be resolutely proposed and advocated for. However, the inclusion of those protections and the extent to which they may be included will be an issue for New Zealand to determine, depending upon the level of market access granted by the EU in areas pertinent to New Zealand's interests. As such, the implications resulting from any implementation of stronger protection also remain unknown.

## *B Purpose of Research and Methodology*

The purpose of this thesis is to identify those TRIPS-plus protections relating to pharmaceuticals and GIs that may be included within an EU-NZ FTA and the implications arising from any implementation of those protections in New Zealand domestic law.

In order to achieve that purpose, this thesis shall conduct a qualitative analysis, combining doctrinal legal analysis and archival research. The researcher proposes that a comparative interpretative analysis of TRIPS-plus protections in recent FTAs negotiated by both parties would identify those protections deemed as acceptable to the parties to be included within an FTA. To this end, the researcher shall conduct a legal comparison between the recently negotiated Comprehensive and Progressive Agreement for Trans-Pacific Partnership (CPTPP),<sup>4</sup> to which New Zealand is a party, and the Comprehensive Economic and Trade Agreement (CETA),<sup>5</sup> to which the EU is a party. This analysis shall be conducted in accordance with art 31 of the Vienna Convention on the Law of Treaties (VCLT).<sup>6</sup> It is also proposed that an analysis of the parties' domestic IP laws and negotiating documents in concluding those agreements will shed light on the context of those FTAs, thereby identifying any common interests or positions regarding IP protection.

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<sup>4</sup> Comprehensive and Progressive Agreement for Trans-Pacific Partnership, Australia-Brunei Darussalam-Canada-Chile-Japan-Malaysia-Mexico-New Zealand-Peru-Singapore-Viet Nam (signed 08 March 2018, entered into force 30 December 2018) [hereinafter CPTPP].

<sup>5</sup> Comprehensive Economic and Trade Agreement, European Union-Canada (opened for signature 26 September 2014, provisionally entered into force 21 September 2017) [hereinafter CETA].

<sup>6</sup> Vienna Convention on the Law of Treaties 1155 UNTS 331 (signed 23 May 1969, entered into force 27 January 1980) [hereinafter VCLT].

It is further proposed that by succinctly identifying those TRIPS-plus protections which could be included within an EU-NZ FTA, a further discussion on the implications for New Zealand will then ensue. This discussion will seek to address such issues as whether New Zealand *should* implement TRIPS-plus protections and, if so, to what extent.

It is important to note that the CPTPP was preceded by the Trans-Pacific Partnership Agreement (TPP Agreement),<sup>7</sup> which has not entered into force. Except where otherwise provided, that agreement has been incorporated in full within the CPTPP.<sup>8</sup> Of significance to this thesis is that specific TRIPS-plus protections were included within that agreement but have subsequently been suspended under art 2 of the CPTPP. While those provisions are not legally enforceable in New Zealand, they serve as indications of TRIPS-plus protections that New Zealand may consider implementing in an FTA and shall therefore be included within this thesis. Any reference to the TPP Agreement without simultaneous reference to the CPTPP should be interpreted as referring to the unenforceable agreement and should be considered non-binding on the parties.

### *C Structure of the Thesis*

This research paper comprises six chapters.

The second chapter considers the evolution and protection of IPRs in the international sphere, with particular reference to pharmaceuticals and GIs. Chapters three and four conduct a comparative interpretative analysis of TRIPS-plus protections relating to pharmaceuticals (chapter three) and GIs (chapter four) within CETA and the CPTPP and within the domestic laws of the parties, identifying those protections which would likely be included within an EU-NZ FTA. Chapter five discusses the implications arising from the implementation of those protections within an EU-NZ FTA, addressing the issues whether New Zealand should implement TRIPS-plus protections and, if so, to what extent. The final chapter concludes the thesis and reflects upon its limitations, as well as providing suggestions for future research.

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<sup>7</sup> Trans-Pacific Partnership Agreement, Australia-Brunei Darussalam-Canada-Chile-Japan-Malaysia-Mexico-New Zealand-Peru-Singapore-United States-Viet Nam (signed 04 February 2016, not in force) [hereinafter TPP Agreement].

<sup>8</sup> CPTPP, above n 4, art 1.1.

## II Global Regulation of Intellectual Property Rights

### A The Evolution of Intellectual Property Rights in the International Sphere

The protection of IPRs is by no means a modern concept. Exclusive control over the ‘fruits of ones labour’ can be traced in theoretical origin to the works of 17<sup>th</sup> century philosopher John Locke, who contended that a property right is a natural right.<sup>9</sup> According to Locke, the exertion of labour to existing resources adds value to that resource, bringing it within the realm of property, the reward for which is ownership.<sup>10</sup> Although conceptualised in the context of physical property, Locke’s theory has been applied to IP as “[i]ntellectual property is no less the fruit of one’s labor than is physical property.”<sup>11</sup> While heavily criticised for failing to provide an adequate account of property rights,<sup>12</sup> Locke’s basic notion of ownership and control over one’s work continues to hold fast in the global IP system.

Historically, legal recognition of IPRs granted a period of exclusive rights only to national right holders. However, the subsequent recognition that IPRs should be protected across national borders led to the conclusion of numerous international agreements throughout the 19<sup>th</sup> and 20<sup>th</sup> centuries.<sup>13</sup> Introducing the concept of national treatment, where a country’s domestic IP laws are applied to both national and foreign right holders without discrimination, these agreements sought to impose minimum standards and harmonise protection across signatory states.<sup>14</sup> Despite some success, the later of these international agreements proved relatively ineffective in standardising and harmonising IP law, leading some states to strengthen the

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<sup>9</sup> John Locke *Two Treatises on Government* (Cambridge University Press, Cambridge, 1988 [1690]) in Christopher May *The Global Political Economy of Intellectual Property Rights: The new enclosures* (2<sup>nd</sup> ed, Routledge, Abingdon, 2010) at 27.

<sup>10</sup> At 27.

<sup>11</sup> Frank H Easterbrook “Intellectual Property is still Property” (1990) 13 Harv JL & Pub Pol’y 108 at 113.

<sup>12</sup> See, for example, Richard A Spinello and Herman T Tavani (eds) *Intellectual Property Rights in a Networked World: Theory and Practice* (Hershey PA, Information Science Publishing, 2005) at 188-190.

<sup>13</sup> See, for example, the Paris Convention for the Protection of Industrial Property (adopted 20 March 1883, as last revised at Stockholm on 14 July 1967) 21 UST 1583, 828 UNTS 305, the Berne Convention for the Protection of Literary and Artistic Works (adopted 9 September 1886, as revised at Paris on 24 July 1971 and amended in 1979) S Treaty Doc No 99-27 (1986), the Madrid Agreement Concerning the International Registration of Marks (1891) 23 UST 1353, 828 UNTS 389, the Rome Convention for the Protection of Performers, Producers of Phonograms and Broadcasting Organisations (signed 26 October 1961, entered into force 18 May 1964) 496 UNTS 43 and the International Convention for the Protection of New Varieties of Plants (signed 2 December 1961, as revised at Geneva on 19 March 1991) S Treaty Doc No 104-17.

<sup>14</sup> Simon Lester, Bryan Mercurio and Arwel Davies *World Trade Law: Text, Materials and Commentary* (2<sup>nd</sup> ed, Hart Publishing, Oxford, 2012) at 740.

relationship between IPRs and trade.<sup>15</sup> The result of their efforts was a binding international agreement which imposed substantive rights and obligations on signatories, coupled with an enforceable dispute resolution mechanism. Accordingly, the acceptance and consolidation of IPRs as rights to be solemnly protected at the international level can be accredited to the TRIPS Agreement, which forms an integral part of the Agreement Establishing the World Trade Organisation (WTO).<sup>16</sup>

### *1 Multilateral inclusion: the TRIPS Agreement*

The premise of the TRIPS Agreement is that insufficient protection of IP will lead to trade distortions caused by piracy and counterfeiting.<sup>17</sup> In order for legitimate trade to develop, owners of IP need adequate protection at the international level. However, the TRIPS Agreement also recognises that excessive IP protection may itself become a barrier to legitimate trade.<sup>18</sup> As such, the TRIPS Agreement seeks to provide a balance by setting down enforceable minimum standards of IP protection that all WTO Members must adhere to, thus setting the floor but not the ceiling.

The TRIPS Agreement builds upon the existing international framework for IP protection by incorporating aspects and principles of previous agreements. This includes the principle of national treatment, which is encapsulated within art 3.1. It also includes the most-favoured nation (MFN) principle; a fundamental principle underpinning the General Agreement on Tariffs and Trade (GATT),<sup>19</sup> the purpose of which is to ensure uniformity by requiring that any privilege or advantage granted to nationals of one WTO Member be accorded to nationals of all WTO Members.<sup>20</sup> The most significant impact of this principle has been in the context of FTAs as, unlike the GATT, the TRIPS Agreement does not contain any specific exception to MFN treatment in that context.<sup>21</sup> This means that the adoption of any additional or stronger IP

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<sup>15</sup> At 740.

<sup>16</sup> Marrakesh Agreement Establishing the World Trade Organisation (15 April 1994) 1867 U.N.T.S 154 [hereinafter WTO Agreement], art II:2.

<sup>17</sup> Daniel Gervais *The TRIPS Agreement: Drafting History and Analysis* (3<sup>rd</sup> ed, Sweet & Maxwell, London, 2008) at 155.

<sup>18</sup> TRIPS Agreement, above n 3, preamble.

<sup>19</sup> General Agreement on Tariffs and Trade 1994 (Marrakesh, Morocco, 15 April 1994), Marrakesh Agreement Establishing the World Trade Organisation, Annex 1A, THE LEGAL TEXTS: THE RESULTS OF THE URUGUAY ROUND OF MULTILATERAL TRADE NEGOTIATIONS 17 (1999), 1867 U.N.T.S 190, 33 I.L.M. 1153 (1994) [hereinafter, GATT].

<sup>20</sup> TRIPS Agreement, above n 3, art 4.4.

<sup>21</sup> See GATT, above n 19, art XXIV. Note that the TRIPS Agreement does not contain a similar provision.

protections under an FTA is not only applicable between the parties to that agreement, but must be granted to all WTO Members alike.

Despite its significant achievement as the first effectively enforceable international IP agreement, the TRIPS Agreement represents a compromise between IP producing (typically developed) and IP consuming (typically developing) countries, therefore many of its general provisions are drafted in a manner designed to balance competing interests. Article 6 affirms the right of each WTO Member to determine for itself the issue of exhaustion of IPRs, which has implications for the parallel importation of IP protected products. In addition, arts 7 and 8 set out the objectives and principles of the TRIPS Agreement, which enable Members to take advantage of flexibilities built into that agreement. This permits Members to act in a manner conducive to their own socioeconomic needs, whilst ensuring a balance between the greater public good and the rights of IP owners.

Of significance to this thesis is that art 1.1 leaves it to individual Members to enact more extensive protection at their own discretion, provided that such protection does not contravene the provisions of the TRIPS Agreement. This is in recognition of the diverse levels of IP protection between individual Members, some of which already imposed higher levels of protection than that negotiated under the TRIPS Agreement. It has been said that this provision indirectly emphasises that the TRIPS Agreement did not achieve the level of protection that some Members desired,<sup>22</sup> but rather the highest level of protection that could be negotiated at the time.<sup>23</sup> For this reason, the provision leaves open the possibility for more extensive protection in subsequent trade agreements.

## 2 *Extending intellectual property rights: TRIPS-plus protections*

Further trade liberalisation at the multilateral level has largely stalled since the failed Doha round of negotiations which commenced in 2001. Since then, the international community has seen a proliferation of FTAs which seek to liberalise trade on a bilateral, plurilateral or regional level. Crucially, more extensive protection of IPRs have been deemed a necessity by highly innovative IP producing states, such as the EU and the United States of America (US), in granting trade concessions within FTAs. Known as ‘TRIPS-plus’ protection, such protection goes beyond the minimum standards set out in the TRIPS Agreement by for example

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<sup>22</sup> Gervais, above n 17, at 164.

<sup>23</sup> Susy Frankel “The Legitimacy and Purpose of Intellectual Property Chapters in FTAs” (2001) 1(1) VUWLRP 1 at 6.

establishing greater subject matter coverage and longer duration of rights, by eliminating or limiting flexibilities established within the TRIPS Agreement, or by requiring protection of forms of IPRs which were not included within the ambit of the TRIPS Agreement.<sup>24</sup> While many of these protections are a reflection of the status quo within IP producing states,<sup>25</sup> this is often not the case for the negotiating partner who is forced to accept higher levels of IPRs that may not correspond to their socioeconomic needs in order to gain access to larger and more affluent markets.<sup>26</sup> Such asymmetrical power relations have led to considerable discussion on whether or not TRIPS-plus protections constitute barriers to trade, as what may be beneficial for trade for one state is not necessarily beneficial for another.

Of pertinence to this research paper are TRIPS-plus protections relating to pharmaceuticals, both patent-related and regulatory, and GIs. Each shall be examined in turn.

(a) Pharmaceuticals: patent protection

Traditionally, pharmaceutical products have been protected by way of a patent, which provides the innovator or right holder with a period of exclusivity in which they alone may produce the product and reap its financial benefits. Patents allow the innovator to recoup the costs associated with researching and developing the product, thereby providing an incentive for innovators to invest in developing pharmaceutical products.<sup>27</sup> The opposing perspective is that, by granting an exclusive right over the product, the innovator holds a monopoly over the price and quantity of the product, thereby reducing public access.<sup>28</sup> An ‘optimum’ patent term of 20 years has been established under the TRIPS Agreement as an international standard to balance competing interests.<sup>29</sup>

Over the past few decades, the cost and time of researching, developing and marketing a pharmaceutical product has increased exponentially. Recent data published by the Pharmaceutical Research and Manufacturers of America estimates that it costs on average USD \$2.6 billion to develop and market one product – up from USD\$179 million in the 1970’s.<sup>30</sup>

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<sup>24</sup> At 7-8 and 12.

<sup>25</sup> At 6.

<sup>26</sup> Susan K Sell “TRIPS-Plus Free Trade Agreements and Access to Medicines” (2007) 28(1) *Liverpool L Rev* 41 at 59.

<sup>27</sup> Meir P Pugatch “The International Regulation of IPRs in a TRIPS and TRIPS-plus World” (2005) 6(3) *JWIT* 431 at 433.

<sup>28</sup> At 433.

<sup>29</sup> TRIPS Agreement, above n 3, art 33.

<sup>30</sup> Pharmaceutical Research and Manufacturers of America *2015 biopharmaceutical research industry profile* (Washington, DC, April 2015) at 35.

This is compounded by an increase in the length of time taken to develop the product and to obtain authorisation by the marketing authority, due to stronger regulations surrounding safety and efficacy in clinical testing. It has been estimated that even in New Zealand the length of time – from patent filing to marketing authorisation – had increased to over ten years in the 1990's from three – four years during the 1960s.<sup>31</sup> Research on the pharmaceutical development process in the US and 15 EU countries estimates this figure to have increased on average to 13.9 years, for products introduced onto the market from the year 2000 onwards.<sup>32</sup> As a result, the global pharmaceutical industry has successfully lobbied for the enactment of extensive IP protection in the domestic laws of IP producing states. Consequently, such protections have been reflected within those state's trade policy, leading to the imposition of TRIPS-plus protections within FTAs.

(i) Patent term: extension/restoration

Article 33 of the TRIPS Agreement establishes a minimum patent term of 20 years – a term which begins on the date the patent application was filed.<sup>33</sup> Due to the time it takes to conduct clinical trials on new products and the competitive nature of the pharmaceutical industry, companies wishing to apply for patent protection for a potential product must do so at the earliest possible time, which is often many years before they can file for marketing authorisation.<sup>34</sup> By the time the pharmaceutical product is introduced onto the market, it has a significantly reduced effective patent life. This means that a pharmaceutical company which obtained a patent for its product has a significantly shorter monopoly period in which to recoup their expenditure.<sup>35</sup> One implication of this is the stifling of innovation, due to reduced expected returns.

Nothing in the TRIPS Agreement requires Members to compensate pharmaceutical companies for delays in approving a patent or in authorising a pharmaceutical product. In order to rebalance the effects resulting from an increased time delay, IP producing states have enacted legal provisions which compensate patent holders for delays caused by the patent office in

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<sup>31</sup> John Parker "Pharmaceutical Patent Term Restoration in New Zealand" (2000) 18(3) *Prometheus* 319 at 322. Note that a pharmaceutical product subject to a 16 year patent during the 1960's had an effective patent life of 12.45 years, while a pharmaceutical product subject to a 20 year patent during the 1990's has an effective patent life of 8.15 years.

<sup>32</sup> Fabio Pammolli, Laura Magazzini and Massimo Riccaboni "The productivity crisis in pharmaceutical R&D" (2011) 10(6) *Nat Rev Drug Discov* 428 at 429.

<sup>33</sup> TRIPS Agreement, above n 3, art 33.

<sup>34</sup> Bryan Mercurio "TRIPS-Plus Provisions in FTAs: Recent Trends" in Lorand Bartels and Federico Ortino (eds) *Regional Trade Agreements and the WTO Legal System* (Oxford, Oxford University Press, 2006) at 229.

<sup>35</sup> At 229.



assessing the patent application or by the marketing authority in examining an application for registration.<sup>36</sup> Known as patent term extension or restoration, or *sui generis* protection, these provisions ‘extend’ the patent term once the basic patent has expired, thereby prolonging the patent holders’ monopoly. While the extension of a patent term may not have serious implications for IP producing states, there is genuine concern for the public health effects in IP consuming states, as those states largely rely on generic products in order to maintain affordable medicine pricing.

(ii) Compulsory licencing

Although patents confer exclusive rights, the TRIPS Agreement not only permits limited exceptions to those rights but also permits ‘other use’ without authorisation of the right holder, subject to several conditions. Known as compulsory licencing, art 31 permits a licence applicant to produce and use the subject matter of a patent predominantly for domestic purposes<sup>37</sup> where they have unsuccessfully sought to obtain authorisation from the right holder on reasonable commercial terms.<sup>38</sup> The requirement to obtain authorisation is waived in the case of a national emergency or other circumstances of extreme urgency or in the case of public non-commercial use.<sup>39</sup> Where a compulsory licence is granted, the right holder must be paid adequate remuneration for the unauthorised use of its IP.<sup>40</sup> Article 31 has not been without controversy or concern, in particular relating to what constitutes a national emergency or other circumstances of extreme urgency and the ability of a Member to supply its own domestic market. In response to concerns, WTO Members adopted the Doha Declaration on TRIPS and Public Health<sup>41</sup> to clarify and reaffirm the rights of Members to use the flexibilities of art 31 in taking measures to protect public health. Of significance, the Doha Declaration affirmed the right of each Member to determine for itself what constitutes a national emergency or other circumstances of extreme urgency.<sup>42</sup> In addition, the Doha Declaration recognised the

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<sup>36</sup> See, for example, Drug Price Competition and Patent Restoration Act 35 USC §156 [hereinafter, Hatch-Waxman Act] for patent term restoration in the United States of America, and Council Regulation (EEC) No 1768/92 of 18 June 1992 concerning the creation of a supplementary protection certificate for medicinal products (1992) OJ L182/1 for *sui generis* protection for pharmaceuticals in the European Union.

<sup>37</sup> TRIPS Agreement, above n 3, art 31(f). See World Trade Organization “Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health” WT/L/540 and Corr.1, 01 September 2003 (Decision of the General Council of 30 August 2003), on the solution for WTO Members with insufficient or no domestic manufacturing capabilities to make effective use of compulsory licencing.

<sup>38</sup> TRIPS Agreement, above n 3, art 31(b) and (f).

<sup>39</sup> Art 31(b).

<sup>40</sup> Art 31(h).

<sup>41</sup> World Trade Organization “Declaration on the TRIPS Agreement and Public Health” WTO Doc. WT/ MIN (01)/DEC/2 (20 November 2001) (Adopted 14 November 2001) [hereinafter “Doha Declaration”].

<sup>42</sup> Para 5.

difficulties faced by Members with insufficient or no manufacturing capacities in the pharmaceutical sector and called for a solution to this problem to be found.<sup>43</sup> The solution was to waive the obligations under art 31 to the extent necessary in order for Members to produce and export pharmaceutical products to an eligible importing Member, primarily least-developed countries.<sup>44</sup> This solution came into force as art 31bis of the TRIPS Agreement in 2017.

Article 31 of the TRIPS Agreement does not oblige Members to issue compulsory licences but rather leaves it for each Member to determine for themselves.<sup>45</sup> Notwithstanding the above and further conditions stipulated in art 31, nor does it limit the circumstances under which a compulsory licence may be issued. Despite this, some IP producing states have sought to directly limit the ability to use compulsory licencing by restricting the grounds on which one may be issued.<sup>46</sup> This has negative implications when such restrictions are included within trade agreements with less innovative or IP consuming states, as it hinders their ability to provide their citizens with access to affordable medicine.

A preliminary examination of both EU and New Zealand domestic law, and provisions relating to compulsory licencing within CETA and the TPP Agreement, indicates that there is no issue of TRIPS-plus protection relating to compulsory licencing between the parties. In fact, both parties support and commit to the post-TRIPS health initiatives domestically and endorse these initiatives within their respective FTAs. As there is no issue here with respect to compulsory licensing, it shall not be specifically examined as part of this thesis.

### (iii) Patent linkage

When applying for marketing authorisation of a new product, a pharmaceutical company may be required to submit their clinical test data in support of their application. While that data must be protected against unfair commercial use and disclosure,<sup>47</sup> many countries allow for the use of that data in support of an application for marketing authorisation of a generic pharmaceutical

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<sup>43</sup> Para 6.

<sup>44</sup> World Trade Organization “Implementation of paragraph 6 of the Doha Declaration on the TRIPS Agreement and public health”, above n 37, para 2.

<sup>45</sup> TRIPS Agreement, above n 3, art 31. Note that art 31 commences “Where the law of a Member allows for other use...”.

<sup>46</sup> See, for example, Australia-United States Free Trade Agreement [2005] ATS 1 (signed 18 May 2004, entered into force 01 January 2005), art 17.9.7 [hereinafter, AUSFTA]. Note that a compulsory licence may only be issued to remedy anti-competitive practices and in the cases of public non-commercial use, national emergency or other circumstances of extreme urgency.

<sup>47</sup> TRIPS Agreement, above n 3, art 39.3.

product, even where the original product is still under patent. In addition, nothing in the TRIPS Agreement specifically addresses the use of a patented product by a generic manufacturer in order to obtain marketing authorisation prior to the expiration of that patent. However, art 30 does authorise limited exceptions to the exclusive rights of the patent holder. This has been interpreted by the WTO Dispute Settlement Body in *Canada – Pharmaceutical Products* to include the use of a patented product by a generic manufacturer when applying for marketing authorisation.<sup>48</sup> This interpretation is consistent with state practice prior to the entry into force of the TRIPS Agreement and is known as the regulatory review exception or ‘Bolar exemption’.<sup>49</sup>

Irrespective, there has recently been a push towards introducing within FTAs TRIPS-plus protections known as patent linkage. In its limited form, this requires the implementation of a notification system whereby a patent holder is informed of an application by a generic manufacturer for marketing authorisation prior to authorisation being granted.<sup>50</sup> In its extreme form, on the other hand, marketing authorities are outright prevented from approving a generic version of the patented product without the consent of the patent holder until the expiration of the patent term.<sup>51</sup> The result is the elimination of a legitimate exception to exclusive rights under the TRIPS Agreement.

Introduction of such provisions represents a significant shift in the traditional position as it removes the responsibility of ‘enforcer’ from the patent holder and delegates that role to marketing authorities instead, ignoring the fact that patents are private rights.<sup>52</sup> This provides a significant benefit to the patent holder as generics are prevented entirely from entering the market, rather than entering at the risk of infringement proceedings. In addition, patent linkage impairs the ability of compulsory licence holders to make use of their licence as products produced under a licence still need to obtain marketing authorisation.<sup>53</sup> Patent linkage provisions, therefore, effectively render a compulsory licence redundant.

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<sup>48</sup> *Canada – Patent Protection of Pharmaceutical Products* WT/DS114/R, 17 March 2000 (Report of the Panel), at 7.84. Note that this exception does not permit the manufacture and stockpiling of drugs prior to the expiration of the patent, at 7.38.

<sup>49</sup> See, for example, Hatch-Waxman Act, above n 36, §271(e)(1) and Patent Act RSC 1985 c P-4, s 55.2(1).

<sup>50</sup> See for example TPP Agreement, above n 7, art 18.53.1(a).

<sup>51</sup> Mercurio, above n 34, at 224.

<sup>52</sup> At 225. See also Carlos María Correa “Implications of bilateral free trade agreements on access to medicines” (2006) 84(5) Bull World Health Organ 399 at 402.

<sup>53</sup> Beatrice Lindstrom “Scaling Back TRIPS-Plus: An Analysis of Intellectual Property Provisions in Trade Agreements and Implications for Asia and the Pacific” (2010) 42(3) NYU J Int’l L & Pol 917 at 950.

(iv) Patentable subject matter: second use patents

Article 27.1 of the TRIPS Agreement provides that a patent may be granted to any invention provided it is new, involves an inventive step and is capable of industrial application. The TRIPS Agreement does not define these concepts, leaving it to individual Members to provide a reasonable interpretation instead. Recently, pharmaceutical companies have utilised this flexibility to seek second use patents for new uses of known therapeutic products. For example, pharmaceutical company Merck & Co Inc successfully claimed patentability of a second medical use in the United Kingdom (UK) in *Actavis v Merck*.<sup>54</sup> Second use patents have since been expressly endorsed by the European Patent Office (EPO).<sup>55</sup>

The argument against second use patents is that it allows pharmaceutical companies to prolong their monopoly by claiming a second use to an existing product, such as a new dosage form or method of use.<sup>56</sup> However, it is arguable that the effect of this is relatively limited as the original patent will still expire and generics may thereafter enter the market, albeit without reference to the new use or dosage form. Nevertheless, some US FTAs require the protection of second use patents.<sup>57</sup> This has the effect of carving out a TRIPS Agreement flexibility by dictating how a Member must interpret provisions within the TRIPS Agreement.

(v) Exhaustion and parallel importation

Article 6 of the TRIPS Agreement affirms the right of each WTO Member to determine for itself the issue of exhaustion of IPRs. This refers to the mode by which the exclusive rights of a patent holder are extinguished through the sale of the patented product. Many countries recognise an international exhaustion regime, where the rights of the patent holder are extinguished upon first placing the product on the market in any country.<sup>58</sup> Unless otherwise prohibited, this has the effect of permitting the practice of parallel importation, where the product is then imported (or reimported) elsewhere without the permission of the patent holder.<sup>59</sup> As patent holders may choose to engage in price discrimination when offering their

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<sup>54</sup> *Actavis UK Ltd v Merck & Co Inc* [2008] EWCA Civ 444.

<sup>55</sup> See G 0002/08 (Dosage regime/ ABBOTT RESPIRATORY) of 19 February 2010, ECLI:EP:BA:2010:G000208..

<sup>56</sup> Lindstrom, above n 53, at 953.

<sup>57</sup> See, for example, AUSFTA, above n 46, art 17.9.1

<sup>58</sup> Lindstrom, above n 53, at 951.

<sup>59</sup> At 951.

product for sale, parallel importation may permit a country to purchase the pharmaceutical product elsewhere at a lower price.

Some IP producing states argue in favour of banning parallel importation and seek to restrict its practice within FTAs. This is evidenced in the Australia-United States Free Trade Agreement, which prohibits importation of a patented product without the patent holders consent where the patent holder has placed restrictions on importation by contract or by other means.<sup>60</sup> Such provisions grant extensive power to the patent holder to contractually restrict a country from acting in the best interests of the general public.

A preliminary examination of both EU and New Zealand domestic law, and provisions relating to exhaustion within CETA and the TPP Agreement, indicates that there is no issue of TRIPS-plus protection relating to exhaustion between the parties. While the EU prohibits parallel importation, New Zealand regulatory law renders it impossible other than by the Crown.<sup>61</sup> Even then, the ability of the Crown to parallel import is restricted by legislative provisions and international pressure.<sup>62</sup> As there is little issue here with respect to exhaustion and consequently parallel importation, it shall not be specifically examined as part of this thesis.

#### (b) Pharmaceuticals: regulatory protection

In the ordinary course of business, information is developed which the business owner has an interest in keeping confidential in order to benefit from the commercial value in keeping it secret.<sup>63</sup> Commonly known as undisclosed information or ‘trade secrets’, such information broadly encompasses technical information, confidential business information and know-how, including industrial processes and formulae, business plans and information as concerns methods.<sup>64</sup> Such information is protected against misappropriation, either by competitors or by those within the business who have been given that information in confidence.<sup>65</sup>

The protection of undisclosed information is encapsulated within art 39 of the TRIPS Agreement, which obligates Members to ensure effective protection of such information

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<sup>60</sup> AUSFTA, above n 46, art 17.9.4.

<sup>61</sup> See Medicines Act 1981, s 32A and Ministry of Health *Regulatory Impact Assessment: Therapeutic Products Regulation - Replacement of Medicines Act 1981 and Medicines Regulation 1984 with a new legislative scheme for therapeutic products – Analysis of specific issues and options* (24 March 2016) at 140-141.

<sup>62</sup> Hansard (5 December 1989) 503 NZPD 14360.

<sup>63</sup> Anna Kingsbury ‘The Trans-Pacific Partnership Agreement and the Protection of Commercial Confidential Information and Trade Secrets in New Zealand Law’ (2016) 38(4) EIPR 237 at 238.

<sup>64</sup> Douglas C Lippoldt and Mark F Schultz *Trade Secrets, Innovation and the WTO* (International Centre for Trade and Sustainable Development, E15Initiative Think Piece, August 2014) at 1.

<sup>65</sup> Kingsbury, above n 63, at 238.

against unfair competition.<sup>66</sup> Article 39.2 requires the protection of undisclosed information against unauthorised disclosure or misappropriation where that information is secret, has commercial value by way of its secrecy and reasonable steps have been taken to ensure its secrecy. In addition, art 39.3 requires the protection of undisclosed pharmaceutical and agricultural chemical test data where such data has been submitted to a governmental agency as a condition for obtaining marketing authorisation. Test data under art 39.3 must be protected not only against unfair commercial use but also “against disclosure, except where necessary to protect the public, or unless steps are taken to ensure that the data are protected against unfair commercial use.”

Article 39.3 requires Members to take positive action in order to protect clinical test data against unfair commercial use and disclosure. There is, however, no obligation to provide exclusive rights in that data. Nevertheless, innovative IP producing states have implemented data exclusivity provisions for a definitive period, during which time a generic manufacturer cannot rely on the originator’s test data in support of their application for marketing authorisation of their generic product.<sup>67</sup> This does not prevent the generic manufacturer from conducting their own clinical trials in order to replicate the originator’s pharmaceutical product, however, the resources and expenditure required to do so makes this option infeasible in practice.<sup>68</sup> As a generic manufacturer must rely on the originator’s clinical test data in order to show bioequivalence with an approved product, data exclusivity has the effect of precluding the entry of a generic product onto the market.<sup>69</sup> It is important to note that data exclusivity operates irrespective of the status of a right holders’ patent. Data exclusivity regimes, therefore, add an additional layer of IP protection by acting as a *de facto* patent where a patent may not otherwise exist.<sup>70</sup>

In addition to data exclusivity, some countries may provide a period of market exclusivity: a period where a generic manufacturer cannot market their product, even after the use of undisclosed clinical test data in support of their application for marketing authorisation has

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<sup>66</sup> TRIPS Agreement, above n 3, art 39.1.

<sup>67</sup> Jerome H Reichman “Rethinking the Role of Clinical Trial Data in International Intellectual Property Law: The Case for a Public Goods Approach” (2009) 13(1) Marq Intell Propr L Rev 1 at 4.

<sup>68</sup> At 5.

<sup>69</sup> At 5.

<sup>70</sup> At 5.

been permitted.<sup>71</sup> This similarly has the effect of extending the monopoly of the right holder and may lead to an informal or *de facto* patent extension.

(c) Geographical indications

GIs are distinctive signs that identify a given product as originating from a particular geographical location. They can be distinguished from a trade mark on the basis of geography, which permits a GI to confer on *all* producers of that product in that particular region the exclusive right to use that distinctive sign in order to identify their product.<sup>72</sup> The place of origin is recognised as essential to the product itself, rendering a unique value to the product by yielding certain qualities or attributes that cannot be obtained or replicated elsewhere.<sup>73</sup> Geographical location thus goes beyond providing a mere reference to place of origin, embodying attributes of quality that are used to increase the economic value of the product through its reputation.<sup>74</sup> It is this notion of *terroir*, the essential link between place of origin and product quality, which provides the underlying basis for granting an IPR in a name.

Unlike other forms of IPRs which are designed to reward innovation and creation, GIs are designed to protect a products' reputation and prevent the dilution of its economic value.<sup>75</sup> GIs reward producers in a given geographical region who follow particular production practices, by offering adequate protection against misappropriation or false representation of that geographical region, both of which are detrimental to the products' reputation and the producer's business. At the same time, a GI denotes the origin and therefore quality of a product to consumers, the false use of which deceives a consumer into purchasing an inferior product.<sup>76</sup> Protection is therefore granted on the basis of two interrelated legal principles: protection against misleading use (consumer welfare) and protection against unfair competition (preserving reputation).<sup>77</sup>

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<sup>71</sup> See, for example, Directive 2004/27 EC of the European Parliament and of the Council of 31 March 2004 amending Directive 2001/83/EC on the Community code relating to medicinal products for human use (2004) OJ L136/34, art 10.

<sup>72</sup> José Manuel Cortés Martín "TRIPS Agreement: Towards A Better Protection for Geographical Indications?" (2004) 30(1) Brook J Int'l L 117 at 117.

<sup>73</sup> Kal Raustiala and Stephen R. Munzer "The Global Struggle over Geographic Indications" (2007) 18(2) EJIL 337 at 338.

<sup>74</sup> C Bramley and JF Kirsten "Exploring the Economic Rationale for Protecting Geographical Indicators in Agriculture" (2007) 46(1) Agrekon 69 at 77.

<sup>75</sup> Martín, above n 72, at 118.

<sup>76</sup> Dwijen Rangnekar *The Socio-Economics of Geographical Indications: A Review of Empirical Evidence from Europe* (UNCTAD-ICTSD, Project on IPRs and Sustainable Development, Issue Paper 8, May 2004) at 14.

<sup>77</sup> At 14.

International protection of GIs was relatively limited prior to their inclusion within the TRIPS Agreement. The TRIPS Agreement represented a fundamental step forward by obligating Members to substantively protect GIs through the enforcement of minimum standards. Article 22.2 obliges Members to provide legal means for interested parties to prevent any use of an indication that misleads the public as to the true geographical origin of the product or any use which constitutes an act of unfair competition, thus incorporating the central legal principles identified above. While art 22 sets out the general provisions for the protection of GIs, art 23 affords additional protection for wines and spirits. Crucially, art 23.1 prohibits the use of expressions including ‘kind’, ‘type’, ‘style’ and ‘imitation’ in relation to a GI when differentiating a similar product from the GI protected product. Members are also required to enter into negotiations concerning the establishment of a notification and registration system in order to facilitate the protection of GIs,<sup>78</sup> and are called upon to negotiate for increased protection of wines and spirits.<sup>79</sup>

The inclusion of GIs within the TRIPS Agreement represented a significant achievement for ‘Old World’ countries, who sought to protect their traditionally established and world-renowned wine and spirit products against place name misappropriation from ‘New World’ countries.<sup>80</sup> Nevertheless, the ideological divide between Old and New World countries has persisted and has prevented both the creation of a notification and registration system and the multilateral entry into negotiations aimed at increasing protection under art 23.<sup>81</sup> This has prompted the inclusion of provisions protecting GIs within FTAs and other trade agreements which seek to secure protection for specific products.<sup>82</sup> In this respect, Old World countries are arguably utilising bilateral and plurilateral trade agreements to establish the registration system mandated under the TRIPS Agreement.

In addition, increased global trade and reduced agricultural subsidies have prompted some Old World countries to advocate for expanded product protection, in particular GI protection for agricultural food products.<sup>83</sup> This approach has been criticised by many New World countries as an attempt to claw back generic terms or invalidate terms that are protected under trade mark

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<sup>78</sup> TRIPS Agreement, above n 3, art 23.4.

<sup>79</sup> TRIPS Agreement, above n 3, art 24.1.

<sup>80</sup> Raustiala and Munzer, above n 73, at 350.

<sup>81</sup> Irene Calboli “Expanding the Protection of Geographical Indications of Origin under TRIPS: Old Debate or New Opportunity?” (2006) 10 Marq Intell Prop L 181 at 194.

<sup>82</sup> See, for example, Agreement between the European Community and Canada on trade in wines and spirit drinks [2004] OJ L35/3 (signed 16 September 2003, entered into force 01 June 2004) [hereinafter 2003 Wines and Spirit Drinks Agreement].

<sup>83</sup> Raustiala and Munzer, above n 73, at 350.



law in other countries.<sup>84</sup> On the other hand, proponents of this approach emphasise the dilution of their reputation through the ‘genericisation’ of their place name.<sup>85</sup> As the TRIPS Agreement protects the use of a GI where it is used in good faith and its continued use precedes the signing of that agreement,<sup>86</sup> such an approach has been criticised as violating the TRIPS Agreement.<sup>87</sup> Nevertheless, the protection of specific foodstuffs and agricultural products has similarly been included within recent FTAs concluded by certain old world countries, in particular the EU.<sup>88</sup>

## *B Towards an EU-NZ FTA*

As mentioned above, the extent to which TRIPS-plus protection is afforded remains a matter for each individual country to determine, having regard to their individual domestic socioeconomic circumstances. For, according to Gervais, “each country is different and therefore should tailor its IP policy to its own need”.<sup>89</sup> Of particular significance for each individual country to determine is the degree to which the rights of producers of IP and the rights of consumers are best balanced, taking into account the wider public good. In this respect, it could be expected that an appropriate balance in an IP consuming state would place greater emphasis on the rights of consumers, as the wider public good would prescribe access to innovative creations. Whereas in an IP producing state, it could be expected that an appropriate balance would place greater emphasis on the rights of producers instead, as the wider public good would promote the creation of innovation. On this basis and given the respective positions of the EU and New Zealand, it could be expected that the positions of the parties in relation to IP protection would be reasonably disparate.

With that being said, New Zealand is a small market economy and shares features with both developed and developing countries.<sup>90</sup> With respect to IP, this means that it is in the unique position that it uses more IP than it produces, yet has the ability to create innovation and has the resources to access IP at higher prices.<sup>91</sup> This allows New Zealand to calibrate laws to

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<sup>84</sup> Calboli, above n 81, at 196.

<sup>85</sup> Irene Calboli and Daniel Gervais *The Socio-Economic Aspects of Geographical Indications of Origins* (paper prepared for the Worldwide Symposium on Geographical Indications, World Intellectual Property Organisation, Budapest, October 20-22, 2015).

<sup>86</sup> TRIPS Agreement, above n 3, art 23.4 – 6.

<sup>87</sup> Calboli, above n 81, at 197.

<sup>88</sup> See, for example, CETA, above n 5.

<sup>89</sup> Daniel J Gervais ‘IP Calibration’ in Daniel J Gervais (ed) *Intellectual Property, Trade and Development: Strategies to optimize economic development in a TRIPS-plus era* (2<sup>nd</sup> ed, Oxford University Press, Oxford, 2014) at 87.

<sup>90</sup> Susy Frankel *Test Tubes for Global Intellectual Property Issues: Small Market Economies* (Cambridge University Press, Cambridge, 2015) at 13-14.

<sup>91</sup> At 3.

specific needs by enhancing innovation in certain areas whilst ensuring consumers retain reasonable access in others.<sup>92</sup> It further allows New Zealand to customise trade agreements in order to ensure that IP protection reflects the appropriate level of development in both trading partners by adopting a mixture of minimum standards and innovation-tailored provisions.<sup>93</sup> Accordingly, it cannot be said that the level of domestic IP protection between the EU and New Zealand will inevitably be so disparate that they are diametrically opposed.

Frankel contends that when entering into trade agreements with larger developed economies, small market economies may agree to adopt higher IP protections than what their domestic socioeconomic situation would suggest appropriate in order to gain trade concessions.<sup>94</sup> In this respect, IP may be used as a trade-off where benefits may be gained in other areas pertinent to the specific interests of the small market economy. It is possible that New Zealand may be prepared to implement stronger IP protection in relation to pharmaceuticals and GIs in order to gain concessions in areas such as agriculture. With this being said, Frankel also contends that domestic IP regimes “only work to support innovation and creativity if they are appropriately framed and calibrated to correlate with development levels and innovation opportunities”.<sup>95</sup> Any consideration of adopting higher IP protection in an EU-NZ FTA must take into account the wider implications that may arise and ensure that adoption would not stifle opportunities to offset costs in key areas or unduly hinder socioeconomic development.

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<sup>92</sup> Gervais, above n 89, at 88.

<sup>93</sup> At 87.

<sup>94</sup> Frankel, above n 90, at 23.

<sup>95</sup> At 210.

### *III Protection for Pharmaceuticals*

#### *A General Introduction*

The following chapter on the protection of pharmaceuticals shall be broken into three sections. The first section shall provide a comparative interpretative analysis of TRIPS-plus protections within CETA, the TPP Agreement and the CPTPP, with the TRIPS Agreement providing a baseline for comparison. This analysis shall be conducted in accordance with arts 31 and 32 of the VCLT. The second section shall provide a comparative interpretative analysis of EU and New Zealand domestic law in order to ascertain the position of the Parties. Recourse will be had to archival materials, including government documents and position papers, in conducting this analysis. The third section shall pull together the main findings of this chapter to identify any challenges or difficulties which may arise and therefore need to be overcome during the course of negotiations.

Any interpretative analysis of an international treaty must be conducted in accordance with the customary rules of interpretation of international law. Codified within the VCLT, art 31.1 sets forth the fundamental interpretative rule, which provides as follows: “A treaty shall be interpreted in good faith in accordance with the ordinary meaning to be given to the terms of the treaty in their context and in the light of its object and purpose.” Article 31 continues by setting out those elements which comprise the context, such as another agreement or document made in connection with the conclusion of the treaty, and other matters which are to be taken into account together with the context.<sup>96</sup> These include any subsequent agreement or practice regarding the interpretation or application of the treaty, and any relevant and applicable rules of international law.<sup>97</sup> Recourse may also be had to supplementary means of interpretation, including preparatory work, in order to confirm the meaning or to ascertain the meaning where it is left ambiguous or leads to an interpretation which is manifestly absurd or unreasonable.<sup>98</sup>

Frankel contends that treaty interpretation is a ‘logical progression’ that must be conducted holistically.<sup>99</sup> This means that the full effect of all the elements within art 31 must be taken into

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<sup>96</sup> VCLT, above n 6, art 31(2) and (3).

<sup>97</sup> Art 31(3).

<sup>98</sup> Art 32.

<sup>99</sup> Frankel, above n 90, at 56.

account, without privileging one over another.<sup>100</sup> Such an approach is prescribed within the fundamental interpretative rule stated above as context, object and purpose will often intermingle and therefore be considered concurrently, while the ordinary meaning will be dependent on the context. Treaty interpretation does not, however, permit the interpreter to read in rights and obligations where the treaty is silent on the matter.<sup>101</sup> In addition, recourse to supplementary material, such as preparatory work or drafting history, must only be done within the strict confines of art 32. This is because the treaty provisions represent the intentions of the parties as negotiated whilst supplementary material will go toward the parties' initial positions.

While drafting history is not a primary consideration within the interpretative process, the positions of the parties are by no means to be dismissed. Treaty provisions reflect competing interests and effective interpretation ought to reconcile those interests to give effect to the parties' intentions.<sup>102</sup> Such intentions are often based on national policy, which in turn influence the international norms. In this respect, the object and purpose of national policy may be relevant to treaty interpretation, though they are not decisive;<sup>103</sup> they are simply one element to be considered within the interpretative process.

## *B Interpretation and Comparative Analysis of TRIPS-plus Protections: CETA, TPP Agreement and CPTPP*

TRIPS-plus protections relating to pharmaceuticals can broadly be divided into two categories: patent protection and regulatory protection.

### *1 Patent protection*

#### *(a) Patent term: extension/restoration*

Article 33 of the TRIPS Agreement provides that “[t]he term of protection available shall not end before the expiration of a period of twenty years counted from the filing date.”<sup>104</sup> It is widely accepted that the TRIPS Agreement represents the floor but not the ceiling.<sup>105</sup> Provided

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<sup>100</sup> At 45.

<sup>101</sup> At 54.

<sup>102</sup> At 44.

<sup>103</sup> At 65.

<sup>104</sup> Footnote omitted.

<sup>105</sup> Note that the TRIPS Chairman's Report of 23 July 1990 contained a clause which would encourage states to extend the term of protection in appropriate cases to compensate for delays caused by the regulatory approval process. This clause was not included in any subsequent drafting materials. World Trade Organization *Chairman's Report to the GNG: Status of work in the negotiating group*, Negotiating Group on Trade-Related

that the minimum patent term of 20 years is complied with, individual states are free to impose longer terms of protection within their domestic law and similarly include such protections within their trade agreements with third parties. Nevertheless, longer terms of protection are considered TRIPS-plus as they mandate a stronger level of protection than the minimum prescribed by the TRIPS Agreement.

CETA makes no reference to a minimum term of protection. Rather, art 20.2 states that the provisions of CETA “complement the rights and obligations between the Parties under the TRIPS Agreement”. This means that it contributes extra elements or is in addition to those provisions of the TRIPS Agreement. As CETA does not alter the minimum term of protection, that stipulated in the TRIPS Agreement prevails.

Article 20.27 of CETA goes beyond that provided in the TRIPS Agreement by prescribing a system of patent term restoration that the parties to CETA are bound to abide by. Known as *sui generis* protection, the parties are required to grant a period of protection in respect of a pharmaceutical product protected by a basic patent in force at the request of the patent holder.<sup>106</sup> This is provided that marketing authorisation has been granted for that product, that product has not previously been the subject of a period of *sui generis* protection, and the marketing authorisation is the first authorisation to place that product on the market of that party.<sup>107</sup> Article 20.27.1 defines ‘basic patent’ as a patent which protects a product as such and which has been designated by the patent holder as the basic patent for the purpose of granting *sui generis* protection. Provided that the three specified conditions are met, art 20.27.2 states that the parties “shall provide a period of *sui generis* protection ... at the request of the holder”. In one respect, this could be interpreted to mean that *sui generis* protection must be granted upon every request made by a patent holder without any other conditions imposed. However, this would be inconsistent with art 20.2.2 of CETA which provides that each party “shall be free to determine the appropriate method of implementing the provisions of this Agreement within its own legal system and practice”. Thus, art 20.27.2 may be seen to provide an inherent flexibility for each Party to determine the conditions to which a request for *sui generis* protection may be subject, provided the system is in place for a request to be made.

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Aspects of Intellectual Property Rights, including Trade in Counterfeit Goods (MTN.GNG/NG11/W/76, 23 July 1990) at 19.

<sup>106</sup> CETA, above n 5, art 20.27.2.

<sup>107</sup> Art 20.27.2.

In addition to the conditions specified in art 20.27.2, art 20.27.3 permits a party to prescribe restrictions to the granting of *sui generis* protection based upon matters of temporality. First, a party may require an application for marketing authorisation to be submitted within a reasonable time in order for *sui generis* protection to be granted. The issue of what is ‘reasonable’ is for each party to determine. Second, a party may stipulate a period of time in which the request for *sui generis* protection must be made, provided it is no less than 60 days from the date on which marketing authorisation was granted. The issue of temporality continues to art 20.27.4 which provides that the period of *sui generis* protection shall take effect at the end of the lawful term of the basic patent. Where there is more than one patent protecting the product, the patent holders must select by agreement which is to operate as the basic patent as there may only be one single period of *sui generis* protection for any given product.<sup>108</sup>

Of most significance to this section is the term of *sui generis* protection, which is set down in arts 20.27.5 and 20.27.6, providing the following:

5. Each Party shall provide that the period of *sui generis* protection be for a period equal to the period which elapsed between the date on which the application for the basic patent was filed and the date of the first marketing authorisation, reduced by a period of five years.
6. Notwithstanding paragraph 5 and without prejudice to a possible extension of the period of *sui generis* protection by a Party as an incentive or a reward for research in certain target populations, such as children, the duration of the *sui generis* protection may not exceed a period of two to five years, to be established by each Party.

To summarise the above, the period of *sui generis* protection prescribed by CETA is the length of time between the filing of the patent and the granting of marketing authorisation, minus five years. This period may not exceed a period of two to five years, to be determined by each party, unless an extension is granted for research in certain target populations such as children. To illustrate, a ten-year period between the filing of a patent for a non-paediatric pharmaceutical product and the granting of marketing authorisation would result in a maximum period of *sui generis* protection of five years or a minimum of two, depending on the party. The result would be the same for a 12-year period between the filing of the patent and the granting of marketing authorisation, as the maximum period cannot exceed five years. However, a ten-year period between the filing of a patent for a pharmaceutical product created within a paediatric

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<sup>108</sup> Art 20.27.4.

investigation and the granting of marketing authorisation would result in a maximum period of five years *sui generis* protection, plus an extension if permitted by the relevant party. It is important to note that while CETA prescribes the process for determining the period of *sui generis* protection, it remains within the purview of each party to determine, firstly, whether an extension may or may not be possible, and secondly, within the parameters of art 20.27.6, the maximum period of the *sui generis* protection.

Article 20.27.8 sets down the subject matter that is covered by the *sui generis* protection, being the pharmaceutical *product* covered by the marketing authorisation and any *use* of that product that has been authorised prior to expiration of the *sui generis* protection. Any modifications to the pharmaceutical product which would alter the active ingredients would not be covered by the *sui generis* protection.<sup>109</sup> This would not, however, prevent a manufacturer from applying for a separate patent based upon the modified active ingredients and thereafter claiming a period of *sui generis* protection for the ‘new’ pharmaceutical product. The *sui generis* protection would, however, extend to a new *use* of a known pharmaceutical product, provided that use has been authorised by the relevant authorities before the expiry of the period of *sui generis* protection.

Akin to CETA, the TPP Agreement makes no reference to the minimum term of patent protection. In accordance with art 1.2.1(a) of that Agreement, the minimum patent term as stipulated in art 33 of the TRIPS Agreement prevails. The TPP Agreement also provides a system of patent term restoration, referred to therein as patent term adjustment. This system has since been suspended by art 2 of the CPTPP and is therefore not enforceable law.<sup>110</sup> Nevertheless, the provisions of the TPP Agreement relating to patent term adjustment remain relevant as an indicator of the provisions New Zealand may consider acceptable within an FTA and shall therefore be examined.

The TPP Agreement provides for two systems of patent term adjustment by distinguishing between the granting of a patent and the granting of marketing authorisation. Article 18.46 covers the former while art 18.48 covers the latter.

Article 18.46 begins by directing each party to “make best efforts to process patent applications in an efficient and timely manner, with a view to avoiding unreasonable or unnecessary

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<sup>109</sup> See art 20.27.1 for the definition of ‘product’.

<sup>110</sup> CPTPP, above n 4, art 2. See the Annex for a list of the provisions suspended.

delays”.<sup>111</sup> In aid of this, art 18.46.2 permits the parties to provide procedures for the expedition of the examination of a patent application at the request of the applicant. Provided the application is processed in an efficient and timely manner in accordance with art 18.46.1, there should, however, be no need to request an expedition of examination. From the ordinary meaning of the language used, it can be seen that the parties intend for patent applications to be processed in a well-organised and favourable period of time, the purpose being to limit any delays that are outside what would be considered a normal timeframe.

Articles 18.46.3 and 18.46.4 set out the operative elements for patent term adjustment in relation to the granting of a patent, providing the following:

3. If there are unreasonable delays in a Party’s issuance of patents, that Party shall provide the means to, and at the request of the patent owner shall, adjust the term of the patent to compensate for such delays.<sup>112</sup>

4. For the purposes of this Article, an unreasonable delay at least shall include a delay in the issuance of a patent of more than five years from the date of filing of the application in the territory of the Party, or three years after a request for examination of the application has been made, whichever is later ...

Article 18.46.3 poses a couple of questions in relation to the meaning of the terms used and their effect. The first being the meaning of ‘unreasonable’ delay, for which a definition for the purposes of this provision is provided in art 18.46.4. The inclusion of the phrase “at least shall include” indicates that the definition provided is considered the minimum standard to be applied by the parties, without setting a maximum. This interpretation is consistent with art 18.5 of the TPP Agreement which states that a party “may, but shall not be obliged to, provide more extensive protection for, or enforcement of, intellectual property rights under its law”. Even so, a minimum of five years must pass before a delay is considered unreasonable. Article 18.46.4 goes on to list matters which the parties may exclude from the determination of such delays, including delays out of the control of or not directly attributable to the marketing authority and delays attributable to the applicant. It is for each party to determine whether or not to exclude these periods of time from the determination of ‘unreasonable’ delays.

A second issue relates to the meaning of the term ‘adjust’ in relation to the term of the patent. In its ordinary usage, ‘adjust’ means to alter or to move something in order to achieve the

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<sup>111</sup> TPP Agreement, above n 7, art 18.46.1.

<sup>112</sup> Footnote omitted.



desired result.<sup>113</sup> Article 18.46, however, provides no guidance on *how* the parties are to adjust the term of the patent. One possible interpretation is for an extension to the patent term itself. Another interpretation could be for the parties to provide a separate and distinct period of *sui generis* protection which would apply at the end of the patent term, similar to that prescribed by CETA. A further interpretation could see the patent term commencing at the time the patent application is approved, rather than at the time the patent application is filed. In addition, art 18.46 does not prescribe the length of time the patent term is to be adjusted by. The result is a provision which provides a substantial degree of flexibility to the parties to determine what is appropriate for their individual circumstances when ‘adjusting’ the patent term.

Article 18.48 begins in the same manner as art 18.46 by directing each party to make “best efforts to process applications for marketing approval of pharmaceutical products in an efficient and timely manner, with a view to avoiding unreasonable or unnecessary delays”.<sup>114</sup> The wording used is identical to art 18.46.1, but for its application to marketing authorisation rather than the processing of patent applications. Similar to art 18.46.2, art 18.48.4 permits the parties to adopt or maintain procedures that expedite the processing of marketing authorisation applications. The intention of the parties can therefore be said to be the same.

Articles 18.48.2 and 18.48.3 set out the operative elements for patent term adjustment in relation to the granting of marketing authorisation, providing the following:

2. With respect to a pharmaceutical product that is subject to a patent, each Party shall make available an adjustment of the patent term to compensate the patent owner for unreasonable curtailment of the effective patent term as a result of the marketing approval process.<sup>115</sup>
3. For greater certainty, in implementing the obligations of this Article, each Party may provide for conditions and limitations provided that the Party continues to give effect to this Article.

Similar to art 18.46.3, art 18.48.2 poses a couple of questions in relation to the meaning of the terms used and their effect. One issue relates to the meaning of the term ‘adjust’ in relation to the term of the patent. As the aim of this provision is analogous to that of art 18.46.3, being the adjustment of the patent term as compensation, the same interpretation for that provision could be applied here. However, footnote 46 (Chapter 18) of the TPP Agreement makes clear that “a

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<sup>113</sup> English Oxford Living Dictionaries, ‘adjust’, <<https://en.oxforddictionaries.com/>>.

<sup>114</sup> TPP Agreement, above n 7, art 18.48.1.

<sup>115</sup> Other footnotes omitted.

Party may *alternatively* make available a period of additional *sui generis* protection ... [which] shall confer the rights conferred by the patent”.<sup>116</sup> This means that the parties consider patent term adjustment and *sui generis* protection as two distinct forms of patent term restoration. It can be inferred that the intention of the parties in relation to the meaning of ‘adjust’ is for the patent term itself to be altered. It is important to note that *sui generis* protection as an alternative is only intended in relation to art 18.48.2; it is not intended in relation to art 18.46.3 as that provision does not provide a similar alternative to patent term adjustment for unreasonable delays in the issuance of a patent.

A second issue relates to the meaning of ‘unreasonable curtailment’, for which no interpretation has been provided by the Parties. This is in direct contrast to art 18.46.4, which provides a minimum definition for unreasonable delay. On this basis, it can be inferred that it is for each Party to determine what is an unreasonable curtailment of the effective patent term. In its ordinary usage, ‘unreasonable curtailment’ means the act of reducing or restricting something beyond what is acceptable or fair.<sup>117</sup> In the context of this provision, curtailment goes towards the temporal effect on the effective patent term, as any delay in the granting of marketing authorisation would result in a restriction or reduction of the effective patent term. The result is a shorter duration of market exclusivity of the pharmaceutical product before the patent expires. However, it is a matter of national interpretation how long a delay may be before it is considered unacceptable or unfair.

Finally, an issue may be raised in relation to responsibility for the unreasonable curtailment of the effective patent term. Article 18.48.2 refers to delays due to the marketing authorisation process rather than the broader process undertaken in order to bring a product to the market. Taking a narrow perspective, this means that only delays attributable to the marketing authority while examining the application for marketing authorisation will be taken into account. An argument could be made that delays brought about through clinical trials or reliance upon third-party marketing authorisation information should be included within an examination of whether there has been unreasonable curtailment of the effective patent term.<sup>118</sup> To accept this argument would, however, result in the examination of elements not specifically required by the TPP Agreement. Moreover, art 18.48.3 permits each Party to provide for conditions or

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<sup>116</sup> Emphasis added.

<sup>117</sup> English Oxford Living Dictionaries, above n 113, ‘unreasonable’ and ‘curtailment’.

<sup>118</sup> See Dr Graeme Jarvis, “Submission on consultation document: Implementation of the Trans-Pacific Partnership Intellectual Property Chapter” (Medicines New Zealand, March 2016) at [11].

limitations in implementing the obligations under art 18.48,<sup>119</sup> which would extend to responsibility for unreasonable curtailment. In any event, this would also be a matter for national interpretation.

A comparative interpretative analysis of the patent term restoration provisions in CETA and those in the TPP Agreement reveals numerous differences between the two agreements. This is not only in relation to detailed sub-clauses and the specific language used, but also differences within the broader structure of the schemes and their application. Despite these disparities, the overall legal effect of both schemes renders them neither irreconcilable nor mutually exclusive.

The scope of the *sui generis* scheme in CETA is broad with no mention as to the extent of coverage, while the patent term adjustment scheme in the TPP Agreement clearly sets the scope of the scheme as being unjustified delays in patent issuance and unreasonable curtailment to the effective patent term by virtue of the marketing authorisation process. The broad scope of CETA does not, however, mean that *sui generis* protection must be afforded to every application that satisfies the basic conditions set out in art 20.27 of that Agreement. To argue otherwise would have the absurd consequence of automatic and unconditional patent term restoration upon request, and therefore there is no justification or need for a set minimum patent term. Article 20.2.2 of CETA provides that it is for each Party to determine the appropriate method of implementing the provisions of that Agreement within its own legal system. This accords each Party the flexibility to determine the scope of *sui generis* protection within its own legal system, provided that it gives effect to its obligations within CETA; being the establishment of a system which enables the granting of a period of *sui generis* protection at the request of a patent holder. In this respect, each Party may choose to limit the scope or maintain a broad scope of application whilst maintaining compliance with CETA.

The periods of time to be considered when examining or calculating a request for patent term restoration also differ between the two agreements. Both CETA and the TPP Agreement take the same start and end point, the former being the patent filing date and the latter the date upon which marketing authorisation is granted. However, while CETA examines the period between those dates as one distinct period of time, the TPP Agreement divides the same period into two distinct periods of time to be examined separately, distinguishing the patent approval process

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<sup>119</sup> For example, time limits for applying for an extension, number of extensions granted, length of the extension and subject matter of the extension.

from the marketing authorisation process. The reason for this distinction could be in recognition that the two processes are separate from each other and that a delay in one process does not necessarily mean that there is a corresponding delay in the other process. In this respect, an applicant for patent term restoration may only claim for the loss they have actually suffered.

Both CETA and the TPP Agreement acknowledge that a period of time will inevitably elapse in the natural course of the combined patent and marketing authorisation processes. CETA therefore subtracts a period of five years from its calculation, being a reasonable amount of time in which to process both the patent and marketing authorisation applications. Similarly, the TPP Agreement disregards a period of five years, only after which it considers the delay in patent issuance to be unreasonable. However, this period of five years only applies with respect to the issuance of the patent; it does not include any delays in the marketing authorisation process which result in unreasonable curtailment of the effective patent term. The TPP Agreement can therefore be seen to recognise that a period of more than five years may pass within the natural course of the combined patent and marketing authorisation processes. The implication of this interpretation is that an applicant for patent term restoration may be more likely to succeed under the *sui generis* scheme in CETA than under the patent term adjustment scheme in the TPP Agreement.

With that being said, CETA imposes a maximum period of *sui generis* protection, being two–five years to be determined by each Party, whereas the TPP Agreement does not specify any maximum period. This means, for example, that an applicant whose patent issuance was delayed for 12 years could only receive a maximum period of *sui generis* protection of five years under CETA, or a maximum of two; while under the TPP Agreement they could receive a maximum of seven years patent term adjustment. Any limitation on the period of patent term adjustment claimable is for each Party to the TPP Agreement to determine for themselves, rather than it being imposed.

While the two schemes take different approaches in relation to the period of patent term restoration and the periods of time examined, it does not necessarily mean that the end results must be significantly different. The failure to specify a maximum period of patent term adjustment in the TPP Agreement does not mean that the parties to that Agreement may not impose limitations in their own legal systems. It merely means that the parties are free to determine any limitations themselves. Similarly, the wide breadth of scope afforded under

CETA does not necessarily mean that the parties to that Agreement have no ability to limit the scope. It merely means that the parties are not limited to a narrower scope should they wish to extend it. In this context, either Party under CETA may choose to limit the scope to unreasonable delays in patent issuance or unreasonable curtailments to the effective patent term, similar to the TPP Agreement. The key consideration is that they have the flexibility to do this should they choose to.

Finally, the form and temporal occurrence of the patent term restoration schemes differ between the two agreements. CETA provides for a *sui generis* scheme of patent term restoration which does not operate as part of the patent term but rather operates separately and of its own right. This period of protection applies at the end of the lawful patent term, upon its expiration. In comparison, the TPP Agreement provides for a patent term adjustment scheme which, as interpreted above, operates to adjust the patent term itself. It also permits a *sui generis* scheme of patent term restoration as an alternative to patent term adjustment where there has been unreasonable curtailment of the effective patent term. This alternative could apply at the end of the lawful patent term, similar to the *sui generis* scheme under CETA, as nothing in the TPP Agreement indicates when this alternative *sui generis* protection would apply.

On the face of it, it makes no significant difference whether the period of patent term restoration applies at the end of the lawful patent term or operates to extend the lawful patent term. However, art 20.27.10 of CETA permits each Party to revoke the *sui generis* protection on specified grounds, including on grounds relating to the withdrawal of marketing authorisation. The implication of this is that were marketing authorisation to be withdrawn, the *sui generis* protection may be revoked even though the basic patent still retains legal effect.<sup>120</sup> The patent itself is not affected as the *sui generis* scheme exists of its own right. Whereas under the patent term adjustment scheme of the TPP Agreement, the patent term itself has been adjusted so any revocation of patent term restoration would require the extrication of the adjusted term from the basic patent.<sup>121</sup> With that being said, the subject matter of the basic patent and that of the patent as adjusted under the TPP Agreement are the same. The only difference is the length of the patent term. In addition, this would only affect any adjustment granted in relation to unreasonable curtailment, as the issue is the revocation of marketing authorisation which does not affect the basic patent. On this basis, extrication would be reasonably straight-forward.

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<sup>120</sup> Note that this scenario would only apply where the lawful term of the basic patent has not yet expired, as the period of *sui generis* protection applies after the expiration of the lawful term of the basic patent.

<sup>121</sup> Note that art 18 of the TPP Agreement makes no reference to revocation and is therefore silent on this issue.

Based upon the above analysis, it is apparent that, while there are differences between the patent term restoration schemes in both agreements, there could be little significant difference in the overall legal effect or application of the schemes. The inherent flexibilities of both agreements means that the two patent term restoration schemes are neither mutually exclusive nor irreconcilable.

(b) Patent linkage

As a measure primarily employed to enhance patent monopoly, patent linkage is not included within the TRIPS Agreement. However, it is increasingly employed within bilateral and plurilateral agreements, including both CETA and the CPTPP, albeit to differing standards. It is important to note that the provisions on patent linkage within the TPP Agreement were not suspended by the CPTPP and therefore remain good law.<sup>122</sup>

Patent linkage is addressed in art 20.28 of CETA, which provides:

If a Party relies on “patent linkage” mechanisms whereby the granting of marketing authorisations (or notices of compliance or similar concepts) for generic pharmaceutical products is linked to the existence of patent protection, it shall ensure that all litigants are afforded equivalent and effective rights of appeal.

CETA does not require the Parties to implement a system of patent linkage. Rather, it sets obligations to ensure equal treatment of litigants where a system of patent linkage does exist. The purpose of this provision is to ensure that both generic and originator manufacturers have equal and effective rights of appeal, so that both manufacturers may challenge a finding by the relevant authority relating to the status of the originator’s patent. In some jurisdictions, including Canada, only the generic manufacturer may appeal an unfavourable decision.<sup>123</sup> The originator manufacturer cannot appeal but may instead initiate patent infringement proceedings once the generic product has entered the market. The aim of this provision is therefore to ensure that all Parties are equal before the law, irrespective of any unintended effect this may have on the entry of generic products onto the market.

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<sup>122</sup> See CPTPP, above n 4, annex, for a list of the suspended provisions. Note that art 18.53 is not included in that list.

<sup>123</sup> See Patented Medicines (Notice of Compliance) Regulations, SOR/93-133, regs 6-7. Note that while the PM (NOC) Regulations do not expressly prohibit an originator manufacturer from appealing an unfavourable decision, the practice is for a Notice of Compliance to be issued immediately after the decision which renders an appeal moot. See Kristina Lybecker *Intellectual Property Rights Protection and the Biopharmaceutical Industry: How Canada Measures Up* (Fraser Institute, January 2017) at 13.

In contrast, the CPTPP prescribes a patent linkage system which must be adhered to where a Party permits the reliance upon prior marketing authorisation in obtaining marketing authorisation for a generic pharmaceutical product. Article 18.53 of the TPP Agreement sets forth this system, which requires the Parties to adopt or maintain one of two prescribed patent linkage systems. The first may be described as a notification system. Article 18.53.1(a) imposes an obligation on the marketing authority to enable notification to a patent holder of an application for marketing authorisation of a generic pharmaceutical product which is made in reliance on the originator products' data. While the marketing authority is under no obligation to provide notice to the patent holder, the system must allow for the patent holder to be notified prior to the granting of marketing authorisation. Notification is only to be enabled where marketing would occur during the term of the patent. In determining whether notification is to be enabled, knowledge of any applicable patents is presumably required. The system must also ensure that the patent holder has adequate time and opportunity to seek remedies prior to the granting of marketing authorisation, and that there are procedures and remedies available for the resolution of disputes.<sup>124</sup>

Unlike CETA, the CPTPP does not impose obligations ensuring equal treatment of litigants in respect of rights of appeal. Rather, the CPTPP mandates the provision of procedures and remedies for the resolution of disputes concerning the validity or infringement of a patent. Reference to both validity and infringement indicates that procedures and remedies shall be available to both Parties, however, what those procedures and remedies entail remains for each Party to determine for themselves.

The second and more restrictive system may be described as a prevention system, as art 18.53.2 operates to prevent or preclude the granting of marketing authorisation for a generic pharmaceutical product where there is an applicable and valid patent. It is important to note that art 18.53.2 makes clear that this system is an alternative to the first, thereby making notification the preferred system. Again, knowledge of any applicable patents is presumably required. Article 18.53.2 also makes clear that preclusion is based upon patent information previously submitted to the marketing authority or direct coordination between the marketing authority and the patent office. While patent information may have initially been submitted to the marketing authority when obtaining prior authorisation, coordination may be necessary to determine whether a pharmaceutical product previously marketed remains under patent.

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<sup>124</sup> TPP Agreement, above n 7, art 18.53.1(b) and (c).

Article 18.53.2 does, however, contain a proviso to the effect that the granting of marketing authorisation shall be precluded “unless by consent or acquiescence of the patent holder.” While consent requires express permission, acquiescence requires acceptance without protest.<sup>125</sup> This means that, provided there is no objection, the marketing authority may still grant marketing authorisation to a generic pharmaceutical product. In practice, this proviso may likely be irrelevant as only in rare cases will a patent holder consent or acquiesce to the granting of marketing authorisation for a product marketed in violation of its patent. However, the implication of the proviso is that a patent holder must object in order for the granting of marketing authorisation to be precluded. This interpretation would suggest that a patent holder must be notified of a pending marketing authorisation application in order to object. The difference between the two systems may therefore be seen as the end result: whether the granting of marketing authorisation is automatically precluded upon objection by the patent holder, or whether the patent holder must seek legal remedies to ensure marketing authorisation is not granted despite their objection.

The most significant difference between the patent linkage provisions in CETA and those in the CPTPP is that the CPTPP obliges Parties to adopt a patent linkage system while CETA does not. Rather, CETA recognises that some Parties may permit such a system without obliging other Parties to adopt one. However, the preferred patent linkage system in the TPP Agreement would see the formation of a notification system which would allow patent holders to seek remedies prior to the granting of marketing authorisation, rather than a system which would preclude the granting of marketing authorisation where there is an applicable patent. Of the two systems, the notification system carries the least impact and, for many Parties, may be implemented with little amendment to domestic laws. In this respect, it could be argued that there is very little practical difference between a provision that recognises a Party’s patent linkage system and a provision that requires very little amendment to a Party’s domestic law in order to be compliant.

(c) Patentable subject matter: second use patents

Article 27.1 of the TRIPS Agreement provides that a patent may be granted to any invention provided it is new, involves an inventive step and is capable of industrial application. The TRIPS Agreement does not define these concepts, leaving it to individual Members to provide

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<sup>125</sup> English Oxford Living Dictionaries, above n 113, ‘acquiescence’.



a reasonable interpretation instead.<sup>126</sup> Recent developments relating to pharmaceuticals have seen the broadening of the interpretation of ‘new’ to include new uses of known therapeutic products, protected as second use patents. While the TRIPS Agreement does not prohibit a Member from adopting a broader interpretation and consequently second use patents, any trade agreement that requires the adoption of such an interpretation is above the requirements of the TRIPS Agreement and may therefore be deemed TRIPS-plus.

Similarly, CETA makes no provision for second use patents. In fact, CETA makes no reference to patentable subject matter at all. The failure to include a provision on patentable subject matter must be interpreted in conjunction with art 20.2.1 of CETA, which provides that the provisions of CETA “complement the rights and obligations between the Parties under the TRIPS Agreement.” This means that in the absence of specific provision, the Parties intended for the rights and obligations under the TRIPS Agreement to prevail with respect to patentable subject matter.

In comparison to CETA, the TPP Agreement does contain a provision on patentable subject matter, found in art 18.37. Overall, the wording used in art 18.37 is very similar to that in art 27 of the TRIPS Agreement. Article 18.37.1 sets forth the same definition of patentable subject matter, which includes the three key elements: new, involves an inventive step and is capable of industrial application. The TPP Agreement similarly contains little assistance on the interpretation of those elements,<sup>127</sup> leaving it largely to each Party to determine for themselves. Given the high degree of similarity between the TPP Agreement and the TRIPS Agreement with respect to patentable subject matter, and the intention of the parties to CETA for the rights and obligations of the TRIPS Agreement to prevail, there is no effective difference between CETA and the TPP Agreement in this respect.

The most significant difference between CETA and the TPP Agreement is the inclusion of a clause relating to second use patents. This is contained in art 18.37.2 of the TPP Agreement, which provides:

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<sup>126</sup> Note that footnote 5 of the TRIPS Agreement provides alternative terms for ‘inventive step’ and ‘capable of industrial application’, being ‘non-obvious’ and ‘useful’, respectively.

<sup>127</sup> Note that footnote 30 (Chapter 18) of the TPP Agreement similarly provides alternative definitions for ‘inventive step’ and ‘capable of industrial application’, which are to be synonymous with the terms ‘non-obvious’ and ‘useful’ respectively. Note also that footnote 30 directs each Party to consider whether the claimed invention would have been obvious to a person skilled or having ordinary skill in the art, having regard to the prior art, when determining inventive step.

Subject to paragraphs 3 and 4 and consistent with paragraph 1, each Party confirms that patents are available for inventions claimed as at least one of the following: new uses of a known product, new methods of using a known product, or new processes of using a known product. A Party may limit those new processes to those that do not claim the use of the product as such.

As evident from the above provision, the Parties to the TPP Agreement confirm that patents are available for three kinds of second uses. A Party must ensure that at least one of those second uses is claimable within its domestic law, although all three qualify for patentability. The first, new use of a known product, can be understood as the “substance x for use in the treatment of disease y”.<sup>128</sup> There is no change to the product itself, but a change to the disease that it is now used to treat. The second, new method of using a known product, can be understood as no change to the chemical composition of the product but a change in the method of administration in its treatment of a disease, for example, from oral administration to intravenous injection. The third, new processes of using a known product, can be understood as “the use of product x for the manufacture of a medicament for the treatment of disease y”.<sup>129</sup> Here, the chemical composition of the product has been changed as it has been used to manufacture a new pharmaceutical product. This third type, known as a ‘Swiss-type claim’, would likely have the most success in satisfying the three elements of patentability as the first two would have difficulty establishing novelty. In both these cases, the new use or new method may be described as ‘suitable for’ the treatment of a disease, but nothing of significance has changed to the product itself for that use or method to be considered ‘new’. However, this would depend on each Party’s interpretation of the three key elements of patentability and their domestic law.

The use of the words “each Party confirms” implies that each Party to the TPP Agreement already permits at least one of the second uses listed in art 18.37.2. The purpose of art 18.37.2 can be seen as the locking-in of existing policies relating to second use patents so that they may not be reversed or amended in a way to limit their endorsement. Article 18.37.2 does not require the Parties to implement anything additional to what is already provided for in their domestic law. The effective difference between the TPP Agreement and CETA therefore lies in the flexibility of the Parties to determine future domestic policies relating to second use patents.

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<sup>128</sup> European Patent Office “Guidelines for Examination in the European Patent Office” (November 2018), Part G – Patentability, Chapter VI – Novelty at 7.1.

<sup>129</sup> At 7.1.

It is important to note that art 18.37.2 has been suspended by the CPTPP and does not apply. The effect of this suspension is that each Party retains the flexibility to determine the issue of second use patents by not locking-in existing policies, but nor does it prohibit their use.

## 2 *Regulatory protection: data and market exclusivity*

While data and market exclusivity are to be treated as their own separate forms of regulatory protection, they often go hand in hand or may be viewed as two sides of the same coin. For this reason, they shall be considered concurrently here.

Article 39 of the TRIPS Agreement sets forth the international standard for the protection of undisclosed data or confidential information (trade secrets), including the protection of pharmaceutical clinical or test data submitted for marketing authorisation. It does not, however, make any reference to market exclusivity. The purpose of art 39 is to protect undisclosed information against unfair competition, described in art 10bis(2) of the Paris Convention as “[a]ny act of competition contrary to honest practices in industrial or commercial matters”. Acts which may constitute unfair competition include acts designed to create confusion as to the goods or activities of a competitor, false allegations designed to discredit a competitor and allegations designed to mislead the public in any way about a competitors’ goods.<sup>130</sup>

Protection for undisclosed clinical or test data is afforded in art 39.3, which requires Members to protect such data against unfair commercial use and disclosure where that data is submitted in order to obtain marketing authorisation for a new pharmaceutical product.<sup>131</sup> Unfair commercial use includes the use of that data by a generic manufacturer when obtaining marketing authorisation for their product, as such use confers on them a significant advantage to the detriment of the originator manufacturer. Article 39.3 makes it clear that protection must be afforded where submission of undisclosed data is a condition for obtaining marketing authorisation. Disclosure may, however, be permitted where it is necessary to protect the public or where steps have been taken to ensure protection against unfair commercial use.

One issue left unresolved by the TRIPS Agreement is how that undisclosed data should be ‘protected’. A helpful interpretation is provided in art 39.2 which states, in relation to the more general undisclosed information, that “natural and legal persons shall have the possibility of

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<sup>130</sup> Paris Convention, above n 13, art 10bis(3).

<sup>131</sup> Note that art 39.3 of the TRIPS Agreement also applies to agricultural chemical products which utilise new chemical entities.

preventing information lawfully within their control from being disclosed to, acquired by, or used by others without their consent”. Even so, this statement relates more to the result or aim of the protection, being the prevention of disclosure, rather than any requirement as to how protection is to be achieved. In addition, art 39.3 does not refer to any appropriate length of time which the data ought to be protected for. This is despite earlier drafts of the TRIPS Agreement including provisions which, if adopted, would have imposed a minimum duration of protection.<sup>132</sup>

Both data and market exclusivity have become common features within plurilateral and bilateral trade agreements, of which CETA and the TPP Agreement are no exception. It is important to note that data and market exclusivity provisions within the TPP Agreement have been suspended by art 2 of the CPTPP. Nevertheless, those provisions remain relevant as an indicator of the provisions New Zealand may consider acceptable within an FTA and shall therefore be examined.

Article 20.29 of CETA sets out the protection of undisclosed data related to pharmaceutical products, providing the following:

1. If a Party requires, as a condition for authorising the marketing of pharmaceutical products that utilise new chemical entities ... the submission of undisclosed test or other data necessary to determine whether the use of those products is safe and effective, the Party shall protect such data against disclosure, if the origination of such data involves considerable effort, except where the disclosure is necessary to protect the public or unless steps are taken to ensure that the data are protected against unfair commercial use.
2. Each Party shall provide that for data subject to paragraph 1 that are submitted to the Party after the date of entry into force of this Agreement:
  - (a) no person other than the person who submitted them may, without the latter’s permission, rely on such data in support of an application for an authorisation during a period of not less than six years from the date on which the Party granted authorisation to the person that produced the data for authorisation ...

Article 20.29.1 utilises very similar language to art 39.3 of the TRIPS Agreement, with the most significant difference being the removal of protection against unfair commercial use from the provision, focusing on protection against disclosure instead. This provides a stricter

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<sup>132</sup> See World Trade Organization *Chairman’s Report to the GNG*, above n 105, Part III, Section 7 at 1A.3 and World Trade Organization “Draft Final Act embodying the results of the Uruguay Round of Multilateral Trade Negotiations, Trade Negotiations Committee” (MTN.TNC/W/35/Rev. 1, 3-7 December 1990), art 42(4A).

standard than art 39.3 of the TRIPS Agreement, as for there to be unfair commercial use a disclosure must have been made. Article 20.29 does, however, like art 39.3 of the TRIPS Agreement, envisage that disclosure may be permitted where steps have been taken to ensure the data is protected against unfair commercial use. While this would not likely provide any assistance to a generic manufacturer who produces products for commercial sale, it may aid manufacturers who produce generic pharmaceutical products under compulsory licences either for the domestic market or for export. Irrespective of the intention behind the manufacture of a generic pharmaceutical product, the product nevertheless needs to be proven safe and effective in order for it be marketed. As both Parties to CETA permit the granting of compulsory licences in their domestic legislation, this exception to the protection against disclosure may be crucial in the event of a national health emergency, either domestically or internationally. The relationship between data exclusivity provisions and compulsory licencing is outside the scope of this thesis; however, it provides the basis for future research.

Article 20.29.2(a) goes beyond the TRIPS Agreement by specifying a period of time for which the undisclosed test data referred to in art 20.29.1 must be protected for; being no less than six years from the date of marketing authorisation. This imposes a minimum period of protection in which the test data may not be utilised by a generic manufacturer in support of their application for marketing authorisation. The resulting period of data exclusivity safeguards the originator manufacturer's product from competition, ensuring the manufacturer alone may reap the benefits during this period. The rationale behind the adoption of a period of six years data exclusivity may be seen as a means to lock-in existing domestic law,<sup>133</sup> so that either Party may impose a longer exclusivity period but may not decrease it below six years.

In addition to specifying a minimum period of data exclusivity, art 20.29.2(a) arguably sets a higher standard of protection by ensuring the protection of undisclosed data against reliance rather than unfair commercial use. Unless the marketing authority actually *uses* the originator manufacturer's data, it is arguable that mere reliance is not use. To contextualise, a generic manufacturer need only prove that their product is bioequivalent to the originator's product. Provided that bioequivalence is proven, the marketing authority may accept the application, thereby relying on the originator's data only to the extent of ensuring that the two products are

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<sup>133</sup> Note that Canada imposes a minimum period of six years data exclusivity while the EU imposes a minimum period of eight years. See Food and Drug Regulations, s C.08.004.1(3) and Regulation (EC) No 726/2004 of the European Parliament and of the Council of 31 March 2004 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use and establishing a European Medicines Agency [2004] OJ L136/1, art 14.11.

indeed the same. According to Correa, to argue that mere reliance is in fact use would introduce an interpretation that was not mandated by the TRIPS Agreement and that would create undue barriers to accessing medicines.<sup>134</sup> For the above reason, protection against reliance arguably affords more protection than protection against unfair commercial use. On the other hand, the practical effect of reliance on that data is to grant a commercial benefit by allowing the competitor to make a profit, therefore reliance arguably ought to nevertheless be considered as unfair commercial use.<sup>135</sup>

The adoption of ‘reliance’ within CETA clarifies the position of the Parties towards the protection of undisclosed data in light of art 39.3 of the TRIPS Agreement. The aim of the provision may therefore be understood as preventing the utilisation of undisclosed data by a generic manufacturer in order to derive a commercial benefit, whether or not the data is actually used or merely relied upon. The exception to this prevention is where express permission to rely on the data has been granted by the owner of the data. As this would lead to increased competition and lost profits to the originator manufacturer, it may be assumed that express permission may often be withheld.

In addition to a six-year period of data exclusivity, CETA provides for a period of market exclusivity. Article 20.29(b) provides the following:

A Party shall not grant an authorisation to any person who relies on such data during a period of not less than eight years from the date on which the Party granted the authorisation to the person that produced the data for the authorisation, unless the person that produced these data provides permission.

While art 20.29(a) pertains to the reliance on undisclosed data in support of an application for marketing authorisation, art 20.29(b) pertains to the granting of that marketing authorisation. In the former, a generic manufacturer may not rely on that data for a period of six years from the date on which marketing authorisation was granted to the data owner. After the six years have passed, the generic manufacturer may rely on that data in support of their application to have their own product marketed. However, art 20.29(b) operates to prevent the granting of marketing authorisation until a period of eight years has passed from the date on which marketing authorisation was granted to the data owner. The result is a six-year period of data

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<sup>134</sup> Carlos Maria Correa *Protection of Data Submitted for the Registration of Pharmaceuticals: Implementing the Standards of the TRIPS Agreement* (Switzerland, South Centre, 2002) at 32.

<sup>135</sup> G Lee Skillington and Eric M Solovy “The Protection of Test and Other Data Required by Article 39.3 of the TRIPS Agreement” (2003) 24(1) *Nw J Int’l L & Bus* 1 at 29-30.

exclusivity, and a further two-year period of market exclusivity, where the data may be relied upon, but the marketing authorisation may not be granted until the full eight years has passed. The practical effect is that the originator manufacturer has an eight-year monopoly on their pharmaceutical product that is protected through CETA's regulatory regime, in addition to or irrespective of the existence of a patent.

Similar to art 20.29(a), the period of market exclusivity may be waived with the express permission of the data owner. Again, the increased competition and loss of profits would render any waiver unlikely. The exception may be in order for the originator manufacturer to market its own generic version of the original product; however, with lack of competition, the purpose would be to obtain authorisation in order to release that product as soon as the period of market exclusivity has ceased and the market is flooded with other generic versions.

Article 18.50.1(a) of the TPP Agreement concerns the protection of undisclosed test or other data relating to new pharmaceutical products, providing the following:

If a Party requires, as a condition for granting marketing approval for a new pharmaceutical product, the submission of undisclosed test or other data concerning the safety and efficacy of the product, that Party shall not permit third persons, without the consent of the person that previously submitted such information, to market the same or a similar product on the basis of:

- (i) that information; or
- (ii) the marketing approval granted to the person that submitted such information,

for at least five years from the date of marketing approval of the new pharmaceutical product in the territory of the Party.

Unlike both the TRIPS Agreement and CETA, art 18.50.1(a) makes no reference to unfair competition or the protection of undisclosed data against disclosure. Instead, the purpose is to prevent the marketing of a generic product where the application is based on information or data previously submitted or the prior marketing authorisation of a pharmaceutical product. The emphasis therefore lies in ensuring that products which do rely on undisclosed data are not marketed based on that data, rather than precluding reliance on that data in support of an application for market authorisation. In this respect, the provision has the primary aim of ensuring market exclusivity rather than data exclusivity. This market exclusivity applies for a period of at least five years from the date of marketing authorisation.

The lack of protection against disclosure does not necessarily mean that the Parties to the TPP Agreement are under no obligation to protect undisclosed test or other data submitted in support of an application for marketing authorisation. All Parties to the TPP Agreement are also WTO Members, therefore they remain bound to comply with art 39 of the TRIPS Agreement. It may therefore be speculated that, as the TRIPS Agreement provides general protection for undisclosed data against disclosure, the Parties deemed it unnecessary to reiterate this in the TPP Agreement.

Article 18.50.1(a) does not expressly distinguish between or refer to either ‘use’ or ‘rely’. Rather it uses the phrase ‘on the basis of’. In its ordinary usage ‘basis’ means the underlying support or foundation for something, such as a process.<sup>136</sup> In any given context, this could include either ‘use’ or ‘rely’ or both, as is the case here. Article 18.50.1(a) provides that a generic product may not be marketed on the basis of undisclosed test or other data previously submitted or prior marketing approval of a pharmaceutical product. In the former, it is the use of the undisclosed data that provides the underlying support for the generic products’ application for marketing authorisation, while in the latter it is reliance on prior marketing authorisation. Similar to CETA, the aim is to prevent the utilisation of undisclosed data, whether that data is actually used or indirectly used by way of reliance on prior marketing authorisation.

Article 18.50 continues by addressing specific concerns relating to the granting of marketing authorisation where there is reliance on undisclosed data or other information. Article 18.50.1(b) precludes the granting of marketing authorisation for a generic product which relies upon prior marketing authorisation that was obtained based upon evidence of prior marketing authorisation of the same product in another territory. In other words, even where the originator manufacturer relies upon prior marketing authorisation of its own product in another territory, a generic manufacturer may still not rely on that marketing authorisation in support of its own application. It may be inferred that this is due to the fact that the undisclosed test or other data has nevertheless been submitted by the originator manufacturer, irrespective of which territory that data was submitted in. Reliance on prior marketing approval in another territory is still reliance on the undisclosed test or other data.

Article 18.50.2 goes on to apply art 18.50.1, with the necessary changes, for a period of at least three years to new clinical information submitted in relation to a new second use of a previously

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<sup>136</sup> English Oxford Living Dictionaries, above n 113, ‘basis’.



approved pharmaceutical product, or for a period of at least five years for a new pharmaceutical product that contains a chemical entity not previously approved in that Party. Finally, art 18.50.3 provides an exception to art 18.50 by permitting a Party to take measures to protect public health in accordance with the Declaration on TRIPS and Public Health, and any waiver or amendment to the TRIPS Agreement done in relation to that Declaration. This may include the granting of marketing authorisation to a generic pharmaceutical product manufactured under art 31bis of the TRIPS Agreement, even where the application was based upon undisclosed test or other data or prior marketing authorisation.

The TPP Agreement also affords specific protection to new biologics, separate from the general protection for new pharmaceutical products. Article 18.51.1 provides the following:

With regard to protecting new biologics, a Party shall either:

- (a) with respect to the first marketing approval in a Party of a new pharmaceutical product that is or contains a biologic, provide effective market protection through the implementation of Article 18.50.1 (Protection of Undisclosed Test or Other Data) and Article 18.50.3, *mutatis mutandis*, for a period of at least eight years from the date of first marketing approval of that product in that Party; or, alternatively,
- (b) with respect to the first marketing approval in a Party of a new pharmaceutical product that is or contains a biologic, provide effective market protection:
  - (i) through the implementation of Article 18.50.1 (Protection of Undisclosed Test or Other Data) and Article 18.50.3, *mutatis mutandis*, for a period of at least five years from the date of first marketing approval of that product in that Party,
  - (ii) through other measures, and
  - (iii) recognising that market circumstances also contribute to effective market protection

to deliver a comparable outcome in the market.<sup>137</sup>

A biologic is a drug created from a living organism, which often consists of large and complex molecules. This is opposed to traditional small molecule pharmaceutical products which are

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<sup>137</sup> TPP Agreement, above n 7, footnote 59: Nothing requires a Party to extend the protection of this paragraph to:  
(a) any second or subsequent marketing approval of such a pharmaceutical product; or  
(b) a pharmaceutical product that is or contains a previously approved biologic.  
Footnote 60 omitted.

chemically synthesised. Biologics require a complex and costly development process, hence the separate and longer period of protection afforded in art 18.51.1(a).

Article 18.51 mandates the effective market protection of biologics with respect to the first marketing authorisation in a Party. It is important to note that art 18.51 only applies to the first marketing authorisation. Footnote 59 (Chapter 18) makes it clear that it does not apply to any second or subsequent marketing authorisation or to a product that contains a previously approved biologic. As to the aim of the provision, while no definition is provided for effective market protection, art 18.51.1 provides two options for how this is to be achieved. The first is through the implementation of art 18.50.1, in compliance with the exception for public health set forth in art 18.50.3.<sup>138</sup> This is to be implemented for a period of eight years instead of the five years set down in art 18.50.1.<sup>139</sup> Alternatively, the Parties may choose to adopt a three-tiered protection scheme, which offers the Parties a level of independent choice in how protection is to be implemented.<sup>140</sup>

The first tier requires the direct implementation of art 18.50.1, in compliance with the exception for public health set forth in art 18.50.3.<sup>141</sup> In addition, protection is to be implemented through other measures and general market circumstances to deliver a comparable market outcome.<sup>142</sup> Article 18.51(b) provides no guidance for the interpretation of ‘other measures’, leaving the provision ambiguous and therefore subject to independent interpretation. As the aim of art 18.50.1 is to prevent the marketing of a generic product which relies on test or other data submitted in support of a previous marketing authorisation, it could be inferred that ‘other measures’ may include any measure which would obtain a similar result. This may include measures that the Parties are already obliged to implement, such as those relating to patent term and patent linkage. It could also include specific measures which would permit marketing authorisation after the initial five-year period in order to manufacture the generic product for the purpose of stockpiling, while preventing the sale of that product for a further specified period of time. The crucial issue for each Party to determine for themselves would be whether those measures provide an outcome ‘comparable’ to an eight-year period of effective market protection. Finally, the third tier recognises the contribution of market circumstances to effective market protection. The development of biosimilars is much costlier than it is for small

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<sup>138</sup> Art 18.51(a).

<sup>139</sup> Art 18.51(a).

<sup>140</sup> Art 18.51(b).

<sup>141</sup> Art 18.51(b)(i).

<sup>142</sup> Art 18.51(b)(ii) and (iii).

molecule generic products, which means that the marketed price of a biosimilar may not be drastically cheaper than for a biologic. This puts pressure on the biosimilar manufacturer who may be less inclined to develop such products, resulting in a lack of competition on the market to the benefit of the biologic manufacturer.

A comparative analysis between the data and market exclusivity provisions of CETA and those of the TPP Agreement highlight numerous differences between the agreements. However, similar to the provisions relating to patent term restoration, those differences do not render the two agreements irreconcilable or mutually exclusive.

The protection of undisclosed data within CETA takes the form of both data and market exclusivity schemes, whilst in the TPP Agreement it only takes the form of the latter. The failure of the TPP Agreement to include a provision relating to data exclusivity does not necessarily mean that the Parties are under no obligation to protect undisclosed test or other data, as they are bound to comply with art 39 of the TRIPS Agreement. In this respect, they are bound to protect such data against disclosure and from unfair commercial use. CETA, on the other hand, provides for a period of data exclusivity, where the Parties to that Agreement may not permit a generic manufacturer to rely on undisclosed data submitted by an originator manufacturer in support of their own application for marketing authorisation. This is beyond the protection offered by art 39 of TRIPS as it prevents mere reliance on the data, without the actual use or disclosure of it.

Despite the omission of a data exclusivity scheme in the TPP Agreement, the practical effect resulting from the schemes of both agreements is identical if the overall intention of the Parties is to prevent the access onto the market of a generic product for a specified period of time, thereby providing a monopoly to the originator manufacturer. Precluding the reliance on data previously submitted by an originator manufacturer prevents the generic manufacturer from applying for marketing authorisation without conducting their own clinical trials. Even after reliance is permitted, marketing authorisation may not be granted for a further specified time under CETA. The effect is that, unless the generic manufacturer conducts their own trials, the generic product is precluded from entering the market until the period of market exclusivity expires. The same result is achieved under the TPP Agreement, which prohibits the granting of marketing authorisation where the application relies on data previously submitted for a specified period of time. Even if the intention of the Parties to CETA is to prevent reliance on the data, the practical effect remains substantially the same; for once a generic manufacturer's

application has been processed in compliance with the TPP Agreement, they still may not market their product until the specified period has expired.

The significant difference between data exclusivity and market exclusivity is therefore not the practical effect, as both provide a monopoly to the originator manufacturer until the period of exclusivity expires. Rather, it relates to timing. Only upon the expiry of the period of data exclusivity can a generic manufacturer submit its application for marketing authorisation. It then has to further wait for this application to be processed and approved before it may market its product. By contrast, under a market exclusivity scheme, a generic manufacturer may submit its application, and have it processed and approved, so that upon the expiry of the period of market exclusivity it may market its product immediately. As both agreements contain periods of market exclusivity, the practical difference between them is not so much the omission of a data exclusivity scheme from the TPP Agreement but the overall period of exclusivity granted under each Agreement and the resulting period of monopoly afforded to the originator product.

The overall length of exclusivity provided under CETA is eight years, with six years data exclusivity and a further two years market exclusivity. In comparison, the TPP Agreement provides a minimum period of five years market exclusivity. Naturally, the practical effect of these periods of exclusivity is that, under the TPP Agreement, a generic product must only wait five years until it may be marketed, whereas a product marketed in a territory which is party to CETA must wait eight years. As previously mentioned, the rationale behind the periods of exclusivity within CETA may be seen as a means to lock-in existing domestic law. The same could similarly be said of the period of exclusivity within the TPP Agreement or may instead be seen as a compromise between parties with diverse laws on this matter.<sup>143</sup> The periods of time specified within each agreement may therefore be seen as the result of negotiation rather than a reflection of each Party's initial objective or intention. In this respect, they are arbitrary periods of time which may be subject to change in future agreements depending on the parties involved.

Finally, there are differences between the agreements relating to the scope of the exclusivity schemes. These differences have principally been addressed above. For example, the aim of

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<sup>143</sup> For example, New Zealand provides a period of 5 years data exclusivity under s23B of the Medicines Act 1981, the United States provides a period of 5 years exclusivity for a new chemical entity and 7 years exclusivity for an orphan drug under s314.108 of the Code of Federal Regulations, and Japan informally provides a period of 8 years data exclusivity for new drugs under art 14-4 of the Pharmaceutical Affairs Act 1960. See also TPP Agreement, above n 7, art 18.83 for the transition periods required by Brunei Darussalam, Malaysia, Mexico, Peru and Vietnam in order to implement art 18.50 or art 18.51, or both.

the exclusivity scheme under CETA is to preclude the reliance on previously submitted data used to support an application for marketing authorisation, as the focus is on data exclusivity. Whereas the aim under the TPP Agreement is to prohibit the marketing of a generic product where its application is based on previously submitted data or prior marketing authorisation, as the focus is on market exclusivity. However, the practical effect of each scheme is the same. Similarly, the language used when referring to the ‘use’ of the data in support of an application for marketing authorisation differs between the agreements. While CETA places emphasis on the ‘reliance’ on previously submitted data, the TPP Agreement places emphasis on applications made ‘on the basis of’ previously submitted data or prior marketing authorisation. As discussed above, the latter phrase incorporates the term ‘rely’ as part of its ordinary meaning and any application made on the basis of prior marketing authorisation is made on reliance rather than actual use. While the terms differ, the effect is the same.

The TPP Agreement, however, contains a separate provision which concerns the protection of undisclosed test or other data relating to biologics, whereas CETA does not include a similar provision. Rather, biologics are incorporated within the data and exclusivity schemes of CETA alongside small molecule drugs. This means that biologics in CETA are protected for a period of eight years, which is comparable to the first and stronger form of protection mandated under the TPP Agreement. Other than providing recognition for the particular situation of biologics, the protection afforded to biologics under the TPP Agreement does not add anything significantly different to the protection afforded to biologics under CETA.

Based on the above analysis, it is apparent that, while there are differences between the data and market exclusivity schemes in the two agreements, there is little significant difference in the overall practical effect of the schemes. The omission of data exclusivity from the TPP Agreement does not render the two exclusivity schemes either irreconcilable or mutually exclusive.

### *C Interpretation and Comparative Analysis of Domestic Law: European Union and New Zealand*

The above section analysed and compared TRIPS-plus protections relating to pharmaceuticals within CETA, the TPP Agreement and the CPTPP, with the TRIPS Agreement providing a baseline for comparison. The purpose of that section was to identify those protections which may be included within an EU-NZ FTA and the existence of any significant differences between the protections which may need to be considered by the Parties during the course of

negotiations. It is recognised by the researcher that international trade agreements are the result of negotiation and as such may be seen as culminations of multiple interests across multiple parties. As interests are often diverse between negotiating parties, international trade agreements may not accurately reflect the domestic position of any given party. The aim of this section is therefore to provide a comparative interpretative analysis of EU and New Zealand domestic law relating to the protection of pharmaceuticals in order to ascertain the respective positions of the parties and to determine any challenges or differences between their respective laws.

First, the protection of IPRs within the EU must be discussed. The EU has the exclusive competence to legislate in areas listed in art 3 of the Treaty on the Functioning of the European Union (TFEU).<sup>144</sup> One of these areas is the common commercial policy, which includes “the commercial aspects of intellectual property”.<sup>145</sup> The Court of Justice of the European Union has interpreted this to include, in its entirety, the TRIPS Agreement.<sup>146</sup> As a result, all external matters relating to IPRs fall within the exclusive competence of the EU. Internal matters, however, are shared between the EU and the Member States.<sup>147</sup> In the present context, the role of the EU is the establishment of the “competition rules necessary for the functioning of the internal market”.<sup>148</sup> While “rules on intellectual property are essential in order to maintain competition undistorted on the internal market”, they do not necessarily constitute competition rules.<sup>149</sup> Unless otherwise expressly stated therein, exclusive EU competence in the internal market may only be exercised within the ambit of the provisions of the TFEU which relate to competition.<sup>150</sup> Within the context of the shared competence, however, the EU may also “establish measures for the creation of European intellectual property rights to provide uniform protection of intellectual property rights throughout the Union”, which includes the establishment of a centralised Union-wide authorisation body.<sup>151</sup> The aim of that provision is

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<sup>144</sup> Consolidated version of the Treaty on the Functioning of the European Union OJ C 202 (07 June 2016) [hereinafter, TFEU].

<sup>145</sup> Art 207.1.

<sup>146</sup> Case C-414/11 *Daiichi Sankyo Co. Ltd and Sanofi-Aventis Deutschland GmbH v DEMO Anonimos Viomikhaniki kai Emporiki Etairia Farmakon* [2013] ECLI:EU:C:2013:520 at 52-59.

<sup>147</sup> TFEU, above n 144, art 4.2(a).

<sup>148</sup> Art 3.1.

<sup>149</sup> Joined Cases C-274/11 and C-295/11 *Kingdom of Spain and Italian Republic v Council of the European Union* [2013] ECLI:EU:C:2013:240 at 22.

<sup>150</sup> At 23.

<sup>151</sup> TFEU, above n 144, art 118.

to provide an EU-wide IP regime, thereby removing barriers relating to national rules and regulations, which co-exists alongside national IP regimes.

IP protections relating to pharmaceuticals have not managed to avoid the complex arrangements highlighted above. This is particularly so in relation to patent protection, which shall be discussed below. As the purpose of this thesis is to identify those protections which may be included within an EU-NZ FTA, the scope of this section shall be limited to legal protection at the EU- or interstate-level. Any reference to national laws will be done for the purpose of interpretation or example only.

Domestic legal protection of pharmaceuticals can also be broadly divided into two categories: patent protection and regulatory protection.

### *1 Patent protection*

Patent law may be considered one of the least harmonised areas of IP law within the EU. That said, attempts to create an EU unitary patent system have achieved a high level of success in recent years, with the entry into force of the EU regulations on the creation of a unitary patent system<sup>152</sup> and the signing of the Agreement on a Unified Patent Court (UPC Agreement).<sup>153</sup> Commencement of this system has, however, been stalled due to outstanding ratifications of the UPC Agreement.<sup>154</sup> For the meantime, patent protection is granted either by way of a national patent or a European patent, the latter being granted centrally under the European Patent Convention (EPC) by the European Patent Office (EPO).<sup>155</sup> The result is a dual-system approach: an inventor may choose to apply for a patent in each Member State they want their invention to be protected in, or they may choose to apply for one single European patent to be applicable in any specified Member State. While the granting of the patent may take place at

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<sup>152</sup> Regulation (EU) No 1257/2012 of the European Parliament and of the Council of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection [2012] OJ L 361/1 and Council Regulation (EU) No 1260/2012 of 17 December 2012 implementing enhanced cooperation in the area of the creation of unitary patent protection with regard to the applicable translation arrangements [2012] OJ L 361/89.

<sup>153</sup> Agreement on a Unified Patent Court OJ C 175/1 (signed 20 July 2013, not yet in force).

<sup>154</sup> See art 89 for entry into force. Note that ratification is required by Germany in order for the Agreement to enter into force. European Patent Office “When will the Unitary Patent system start?” <[www.epo.org/law-practice/unitary/unitary-patent/start.html](http://www.epo.org/law-practice/unitary/unitary-patent/start.html)>.

<sup>155</sup> Convention on the Grant of European Patents 1065 UNTS 199 (signed 05 October 1973, entered into force 07 October 1977, as revised by the Act revising Article 63 EPC of 17 December 1991 and the Act revising the EPC of 29 November 2000) [hereinafter EPC].

either level, a European patent is to “have the effect of and be subject to the same conditions as a national patent”.<sup>156</sup>

It is important to note that, while signatories of the EPC include all current Member States of the EU, the EPO is an intergovernmental organisation and is not an institution of the EU. However, the creation of an EU unitary patent has expressly occurred under the auspices of a ‘special agreement’ in accordance with the provisions of the EPC,<sup>157</sup> and shall take effect as a *European patent which benefits from unitary effect*.<sup>158</sup> In addition, the EPC establishes a system of law, common to those party to the Convention, for the granting of patents.<sup>159</sup> This includes subject matters relating to the granting of patents which are in compliance with the TRIPS Agreement and which fall in their entirety within the exclusive competence of the EU. For these reasons, the EPC shall be considered in this section as EU domestic law, in so far as it is applicable in this context.

(a) Patent term: extension/restoration

Article 63(1) of the EPC provides that “the term of the European patent shall be 20 years from the date of filing of the application”. This is consistent with the TRIPS Agreement. Article 63(2) goes on to provide that nothing in art 63(1) limits the “right of a Contracting State to extend the term of a European patent, or to grant corresponding protection which follows immediately on expiry of the term of the patent”. This can be interpreted to mean an extension of the patent term itself or the granting of additional protection, such as *sui generis* protection. It is important to note that art 63 does not oblige parties to extend or grant corresponding patent protection after the expiry of the patent term. Rather, the use of the phrase “nothing ... shall limit the right” indicates that the parties to the EPC have the right to enact such laws at their discretion, which is not affected by the imposition of a 20-year patent term. Where a party does enact such laws, however, those laws apply to European patents under the same conditions as those applying to national patents.<sup>160</sup>

Patent term restoration is mandated within the EU under Regulation No 469/2009.<sup>161</sup> Recognising the insufficient period of effective patent protection afforded to pharmaceutical

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<sup>156</sup> Art 2(2).

<sup>157</sup> Art 142(1).

<sup>158</sup> Regulation (EU) No 1257/2012, above n 152, art 3.1.

<sup>159</sup> EPC, above n 155, art 1.

<sup>160</sup> Art 63(2).

<sup>161</sup> Regulation (EC) No 469/2009 of the European Parliament and of the Council of 6 May 2009 concerning the supplementary protection certificate for medicinal products (Codified version) [2009] OJ L 152/1. Note that



products within the EU,<sup>162</sup> the Regulation prescribes rules concerning the granting and conditions of a supplementary protection certificate (SPC), effective as corresponding patent protection after the expiry of the patent term. An SPC is available for any pharmaceutical product protected by a patent currently in force and which has obtained marketing authorisation, provided both SPC and marketing authorisation are the first of their kind granted to that particular product.<sup>163</sup> Article 5 makes clear that the SPC “shall confer the same rights as conferred by the basic patent and shall be subject to the same limitations and the same obligations”, thereby having the same effect.

The protection conferred by an SPC extends only to the product covered by the market authorisation and for any use of that product authorised prior to the expiry of the SPC.<sup>164</sup> This has implications for second use patents, as the SPC would extend to that second use provided that patent is obtained prior to the expiry of the SPC. This is irrespective of whether the holder of the second use patent and the SPC are the same. An SPC would not, however, be applicable to a second use patent covering a product which has already been the subject of an SPC; the emphasis being the *product*, not the patent.

Article 13 reinforces that the SPC takes effect at the end of the patent term and sets forth the method for determining the duration of the certificate; being the period between the filing of the patent application and the granting of market authorisation, minus five years. Notwithstanding that calculation, the overall duration of the SPC may not exceed five years.<sup>165</sup> This may, however, be extended by a period of six months where the patent relates to a product developed in order to meet the needs of the paediatric population.<sup>166</sup>

Comparing Regulation No 469/2009 with the *sui generis* protection conferred under art 20.27 of CETA, it is evident that there is a high degree of similarity between the two documents. As Canada had no domestic patent term extension scheme in force prior to the enactment of CETA, it can be inferred that the *sui generis* protection within CETA is a broad reflection of EU law. This does not necessarily mean that the interests of Canada are not also reflected within those

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supplementary protection certificates have been available since 1992 under Council Regulation (EEC) No 1768/92, above n 36.

<sup>162</sup> Regulation (EC) No 469/2009, above n 161, preamble at (4).

<sup>163</sup> Art 3.

<sup>164</sup> Art 4.

<sup>165</sup> Art 13.2.

<sup>166</sup> Art 13.3. Note that this extension may only take effect where art 36 of Regulation (EC) No 1901/2006 of the European Parliament and of the Council of 12 December 2006 on medicinal products for paediatric use and amending Regulation (EEC) No 1768/92, Directive 2001/20/EC, Directive 2001/83/EC and Regulation (EC) No 726/2004 [2006] OJ L 378/1 applies.

provisions. It may be that the established patent term restoration scheme of the EU was deemed appropriate by both parties to CETA, with only minor adjustments necessary in order to suit the particular interests of Canada.

New Zealand also provides a minimum term of patent protection of 20 years. This is encapsulated within s 20(1) of the Patents Act 2013 and applies from the patent date, being “the filing date of the relevant complete specification”.<sup>167</sup> Unlike the EU, New Zealand does not provide for patent term extension or restoration. As part of its obligations under arts 18.46 and 18.48 of the TPP Agreement, however, New Zealand passed legislation in order to enact a patent term extension scheme.<sup>168</sup> This scheme would permit the granting of patent term extensions where there are delays in the granting of the patent or where there is unreasonable curtailment of the effective patent term as a result of the marketing authorisation process. While the legislation has been passed, it has not yet entered into force; nor will it until the TPP Agreement enters into force.<sup>169</sup> As the US has notified that it has no intention of becoming a Party to that Agreement, it is uncertain whether the legislation may ever enter into force.

Comparing the domestic legal systems of the EU and New Zealand, it is clear that any difficulty in the area of patent term will be in relation to a patent term extension/restoration scheme. This is evident by the fact that New Zealand has no such scheme, as opposed to the protection afforded under the EU’s SPC scheme. In addition, the high degree of similarity between the EU domestic legal position and the *sui generis* protection afforded under CETA emphasises the interest of the EU in including such provisions within their FTAs. The challenge for negotiators during the course of negotiations will therefore be in determining whether New Zealand *should* enact a patent term extension or restoration scheme and, if so, to what extent.

#### (b) Patent linkage

European Union law neither expressly permits nor prohibits patent linkage. It does, however, implicitly prohibit patent linkage by reference to the marketing of generic pharmaceutical products. Directive 2001/83/EC provides that an applicant for marketing authorisation need not provide the results of pre-clinical tests and clinical trials if the applicant can demonstrate that their product is a generic of a reference (originator) pharmaceutical product which has

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<sup>167</sup> Patents Act 2013, s 103(1)(a). See s 5 for interpretation of ‘patent date’, which directs viewers to s 103.

<sup>168</sup> Trans-Pacific Partnership Agreement Amendment Act 2016 (not in force).

<sup>169</sup> S 2(2).

been authorised within the EU for no less than eight years.<sup>170</sup> Article 10.1 continues on to state that a generic product “shall not be placed on the market until ten years have elapsed from the initial authorisation of the reference product”.

In order to utilise this abridged procedure for marketing authorisation, a generic manufacturer must demonstrate bioequivalence to the originator product. This requires the generic manufacturer to engage in acts which run the risk of infringing the patent. Article 10.6 was therefore introduced to exempt from patent infringement the conducting of “necessary studies and trials” in order to utilise the abridged procedure. In other words, a generic manufacturer may conduct tests in relation to the originator product in order to develop a generic pharmaceutical product where it may then use those tests to apply for marketing authorisation. The justification for this procedure is to ensure the speedy entry onto the market of generic pharmaceutical products upon the expiry of the patent of the originator product.

The effect of art 10 is to permit the development, application and granting of marketing authorisation for generic pharmaceutical products – all during the lawful term of the patent. This is emphasised by the phrase “without prejudice to the law relating to the protection of industrial and commercial property” in art 10.1, which acknowledges the existence of conflicting protection, being the patent term. It is further emphasised by the express exemption from patent infringement of tests and studies under art 10.6. The European Commission has confirmed the effect of art 10 in a Reasoned Opinion under EU infringement proceedings against Italy, which sought to prohibit the submission of applications for marketing authorisation until one year prior to the expiry of the patent term of the originator product.<sup>171</sup> As the processing of marketing authorisation procedures can be carried out without being affected by laws relating to the protection of industrial and commercial property under art 10.1, Italy was bound to ensure compliance with EU law.<sup>172</sup>

Once marketing authorisation has been granted and, in accordance with art 10.1, ten years have passed since the initial authorisation of the originator product, the generic product may be placed on the market, albeit at the risk of infringement proceedings. The Directive does not impose an obligation on any person or body to provide notification to the patent holder of the

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<sup>170</sup> Directive 2001/83/EC of the European Parliament and of the Council of 6 November 2001 on the Community code relating to medicinal products for human use [2001] OJ L 311/67, art 10.1.

<sup>171</sup> European Commission “Pharmaceuticals: Commission calls on Italy to comply with EU rules on marketing authorisation of generic drugs” (press release, 26 January 2012).

<sup>172</sup> European Commission “Pharmaceuticals: Commission calls on Italy to comply with EU rules on marketing authorisation of generic drugs” (press release, 26 January 2012).

entry onto the market of a generic pharmaceutical product. This means that a patent holder may be unaware that a generic pharmaceutical product has been placed on the market in breach of its patent, thereby delaying the initiation of infringement proceedings. The traditional approach is to leave the responsibility for the enforcement of private rights to the right holder, therefore, the failure to provide notification is by no means a new or unique practice.

It must be noted that, while Directive 2001/83/EC sets forth obligations regarding generic pharmaceutical products, it is for each Member State to implement those obligations into domestic law.<sup>173</sup> This may result in differences relating to application, interpretation and legal effect, however, such differences are permissible provided there is compliance with the obligations set out in the Directive.

New Zealand does not specifically provide for patent linkage; however, it is required to enact a patent linkage system in order to implement its obligations under the CPTPP. As discussed above, art 18.53 of the TPP Agreement obliges the Parties to adopt a patent linkage system by either providing a system of notification informing a patent holder when a submission is made for marketing authorisation for a generic version of their patented product, or by precluding the granting of marketing authorisation to a generic pharmaceutical product unless by consent or acquiescence of the patent holder. Article 18.53 was not suspended under the CPTPP and is therefore binding upon New Zealand.

Irrespective of this, it is considered that no legal change is required to ensure compliance with this obligation as the “current law and practice already satisfies these requirements through the information Medsafe publishes on its website, the availability of injunctive relief and the time it takes Medsafe to process applications”.<sup>174</sup> As no provision relating to patent linkage was included within the Comprehensive and Progressive Agreement for Trans-Pacific Partnership Amendment Act 2018, it may be inferred that, indeed, no legislative change was required. It is important to note that New Zealand’s obligations under art 18.53.1(a) of the TPP Agreement (and subsequently the CPTPP) is to provide for “a system to provide notice to a patent holder *or to allow for a patent holder to be notified.*”<sup>175</sup> The latter does not strictly require that express notification be provided to the patent holder, but rather that the patent holder is made known

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<sup>173</sup> Note that while EU Treaties and Regulations are directly enforceable in each Member State, Directives are not.

<sup>174</sup> Ministry of Foreign Affairs and Trade “Understanding CPTPP: Intellectual Property” <<https://www.mfat.govt.nz/en/trade/free-trade-agreements/free-trade-agreements-in-force/cptpp/understanding-cptpp/intellectual-property/>>.

<sup>175</sup> Emphasis added.

of the submission for marketing authorisation of a generic version of its product. Hence why the publication by Medsafe of information on its website is considered to satisfy in part the patent linkage obligations under the CPTPP. Based on the above, it may be said that patent linkage only applies within New Zealand to the extent that it provides for notification to a patent holder when a submission is made for marketing authorisation for a generic version of their patented product and ensures sufficient time and opportunity for that patent holder to seek injunctive relief.

Comparing the legal systems of the EU and New Zealand in relation to patent linkage, it is evident that there is little significant difference between the two systems. While the EU does not permit patent linkage, New Zealand is only obliged to implement it in its weakest sense. The main difference between the legal systems is the requirement, or lack thereof, to provide a system of notification to the patent holder prior to the granting of marketing authorisation for a generic pharmaceutical product. However, even this requirement may be satisfied by providing for a system which makes known the existence of a submission for marketing authorisation for a generic pharmaceutical product, without requiring that express notification be provided to the patent holder. The onus is, therefore, on the patent holder to ensure it makes itself aware that a submission for marketing authorisation has been made. While EU law does not require a similar system of notification, there is nothing to prohibit Member States from implementing one in implementing their obligations under Directive 2001/83/EC. Such a system may similarly require the marketing authority to publish on its website submissions for marketing authorisation which involve a generic version of an originator product, thereby providing a system of notification.

The second main difference relates to timing: to wit, where the New Zealand patent linkage system ensures sufficient time and opportunity for a patent holder to seek injunctive relief prior to the granting of marketing authorisation. Whereas in the EU, the ability of a patent holder to seek injunctive relief would only take effect *after* the granting of marketing authorisation and in accordance with the applicable domestic law.<sup>176</sup> The underlying premise for seeking injunctive relief is to prevent infringement or the continued infringement of a patent, which

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<sup>176</sup> Note that art 9 of the Enforcement Directive permits a Member State to issue interlocutory injunctions intended to prevent any imminent infringement of an intellectual property right, in addition to injunctions aimed at prohibiting the continuation of infringement. Whether or not a Member State permits interlocutory injunctions or the extent to which they impose conditions on the granting of one, is a matter for each Member State to determine for themselves. See Directive 2004/48/EC of the European Parliament and of the Council of 29 April 2004 on the enforcement of intellectual property rights [2004] OJ L 157/45.

implies that a patent has been or is at risk of being breached. The issue of timing therefore goes towards preventing a breach of patent before there is even an imminent threat of that breach occurring. Irrespective of this, the grant of an injunction is entirely a matter for the national judicial authorities to determine in each individual case, and the timing of proceedings does not dictate whether or not an interlocutory injunction will be granted.

Based on the above, it is unlikely that there will be any difficulty in the area of patent linkage going forward in the negotiations for an EU-NZ FTA.

(c) Patentable subject matter: second use patents

Similar to art 27 of the TRIPS Agreement, art 52(1) of the EPC provides that European patents are to be “granted for any inventions, in all fields of technology, provided that they are new, involve an inventive step and are susceptible of industrial application”. Unlike the TRIPS Agreement, however, the EPC provides guidance for the interpretation of each element, rather than providing a mere synonymous term. Of pertinence to second use patents is the interpretation of ‘new’.

Novelty is considered under art 54 of the EPC, which provides that an invention is “considered to be new if it does not form part of the state of the art”.<sup>177</sup> Article 54(2) continues by providing that the state of the art comprises “everything made available to the public by means of a written or oral description, by use, or in any other way, before the date of filing of the European patent application”. In other words, an invention is novel if it has not been disclosed prior to the patent application date.<sup>178</sup> Article 54(4) provides an exception to this general rule by permitting the patentability of a known substance or composition if that substance or composition has not been previously disclosed for use in a method referred to in art 53(c).<sup>179</sup> The justification for this exception lies in the novelty involved in discovering its application for a first medical use. The second and more recent exception to this general rule is for second medical uses.

Over the years, the interpretation of ‘novelty’ has been expanded to include second use patents, which recently have been granted for inventions which would ordinarily not be considered

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<sup>177</sup> EPC, above n 155, art 54(1).

<sup>178</sup> Note that a disclosure made in the six months preceding the filing of the patent application shall not be taken into consideration if that disclosure was due to an evident abuse in relation to the applicant or the invention was displayed at an officially recognised international exhibition in accordance with the Convention on international exhibitions. See EPC, above n 155, art 55.

<sup>179</sup> Being methods of treatment of the human or animal body by surgery or therapy and diagnostic methods practiced on the human or animal body.

patentable under art 53. The earliest use of such patents were known as ‘Swiss-type claims’, which are now covered under art 54(5) of the EPC. The difference between the former Swiss-type claims and art 54(5) is that the former based its claim on the use of a known substance or composition in the *manufacture of a medicament* for a new medical use, while the latter bases its claim on the use of the known substance or composition *for a new medical use*, providing a broader scope.

Article 54(5) of the EPC permits the granting of a patent for a second or further medical use in a method referred to in art 53(c), provided that the new use is novel and inventive. Similar to that under art 54(4), the novelty lies in discovering the second medical use of the known substance or composition. Under art 53(c), methods for treatment by surgery or therapy and diagnostic methods are excluded from patentability. The justification for this exclusion is that medical practitioners should not be prevented from administering suitable medication for fear of patent infringement.<sup>180</sup> However, the products *for use* in any of these methods are not excluded from patentability. Therefore, in applying for a patent under art 54(5), the claim must indicate precisely the use which the patent shall apply to. That said, there is seemingly little limitation on the scope of the use. Article 54(5) provides that it applies to “any specific use in a method”, provided that the use be a medical one. The result is that a claim in the broad form of ‘substance X for use in the treatment of [leukaemia]’ would be considered acceptable.

What has traditionally been considered unacceptable, on the other hand, are claims in the form of ‘use of substance X for the treatment of [leukaemia]’. The reason for this is that the patent claim is for use *in a method of treatment* rather than the use of a substance *in the treatment* of a disease. Such claims have also traditionally included the delivery of non-novel pharmaceutical products; delivery being a form of method. However, in *Actavis v Merck* the UK Court of Appeal held that a dosage regime may be patentable as the claim relates to a different method of using a known substance or composition for the treatment of a particular disease.<sup>181</sup> In other words, the novelty is in the method of using the substance or composition for treatment, rather than merely its use for treatment. The EPO has confirmed the patentability of dosage regimes for European patents in its decision G 002/08 (Dosage regime/*Abbott Respiratory*), acknowledging, however, that the new regime would have to show a particular

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<sup>180</sup> Case G 0002/08 (Dosage regime/ *Abbott Respiratory*), above n 55, at 5.3

<sup>181</sup> *Actavis v Merck*, above n 54, at 6-7.

new technical effect to that which is already disclosed in the state of the art in order to satisfy the ‘inventive step’ requirement.<sup>182</sup>

Despite the broadening scope of second use patents, their legal protection and effect is diminished by market practicalities and EU regulatory law. Article 11 of Directive 2001/83/EC permits the carving out from marketing authorisations of generic pharmaceutical products, those parts of the summary product characteristics referring to indications or dosage forms which are still under patent. This means that a generic pharmaceutical product may be authorised for an off-patent use without indicating in its labelling or packet leaflet its suitability for a use that remains under patent. Known as ‘skinny-labelling’, this enables a generic manufacturer to avoid the risk of patent infringement by limiting the marketing authorisation for the generic product.<sup>183</sup> While this carve-out may be welcome to originator manufacturers, the practical effect is that the generic product may often be nonetheless dispensed by pharmacists to patients for a patented use, as many prescriptions refer to the active ingredient in the product, rather than the product’s name. This presents difficulties in evidencing patent infringement, as the omission of the patented use from the summary product characteristics eliminates any claim for direct infringement. While the issue of second use patent infringement is outside the scope of this research paper, it presents an opportunity for future research in this field.

New Zealand also provides patents for all inventions that are novel, involve an inventive step, and are useful.<sup>184</sup> This is subject to the proviso that the invention is a manner of manufacture within the meaning of s 6 of the UK Statute of Monopolies 1624:<sup>185</sup> being not contrary to law, mischievous to the state or generally inconvenient.

Novelty is defined in s 6 of the Patents Act 2013 as not forming part of the prior art base, which means “all matter (whether a product, a process, information about a product, or anything else) that has at any time before the priority date of that claim been made available to the public”.<sup>186</sup> In compliance with New Zealand’s obligations under art 18.38 of the TPP Agreement, a grace period for any public disclosure made within the 12 months prior to the filing of the patent application was introduced under s 77 of the Comprehensive and Progressive Agreement for

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<sup>182</sup> Case G 0002/08 (Dosage regime/Abbott Respiratory), above n 55, at 6.3.

<sup>183</sup> Case C-423/17 *Staat der Nederlanden v Warner-Lambert Company LLC* [2019] ECLI:EU:C:2019:125 at 43.

<sup>184</sup> Patents Act 2013, s 14(b) and (c).

<sup>185</sup> S 14(a).

<sup>186</sup> S 8.



Trans-Pacific Partnership Amendment Act 2018. Any public disclosure made within those 12 months is to be disregarded for the purposes of the prior art base.<sup>187</sup>

Similar to the EU position, New Zealand also permits the granting of second use patents but as a Swiss-type claim. This was confirmed by the Commissioner of Patents in a practice note in 1997 after reviewing international practice and trends in this field, having disallowed a claim for a Swiss-type claim in 1990.<sup>188</sup> This practice note was approved by the Court of Appeal in *Pharmaceutical Management Agency Ltd v Commissioner of Patents*, where it was held that there can be novelty in the discovery of unrecognised properties of known pharmaceutical products.<sup>189</sup> In his judgement, Gault J examined the position of the EU and argued that the only difference in the law and practice between the EU and New Zealand in this field is where novelty is perceived to reside; novelty residing in the use in the EU and the product in New Zealand.<sup>190</sup> In extending novelty to include second or further medical use, he emphasised the blurring of the distinctions between use and product and highlighted the difficulty in reasoning why novelty cannot be recognised as lying in the use, where he argued it truly lies.<sup>191</sup>

Again, similarly to the EU, New Zealand has excluded from patentability methods for treatment. While the broader question of patentability of methods for treatment was not an issue for the court in *Pharmaceutical Management Agency Ltd v Commissioner of Patents*, Gault J commented that the exclusion of methods for treatment from patentability in New Zealand is now only supported on policy or moral grounds.<sup>192</sup> The Court of Appeal in *Pfizer Inc v Commissioner of Patents*, however, respectfully disagreed with that obiter observation in holding that the exclusion remains sound law, basing their decision on established case law and statutory interpretation.<sup>193</sup> The introduction of s 16(2) in the Patents Act 2013 has rendered this issue moot by expressly excluding from patentability methods for treatment, although the products for use in any method remain patentable.

What remains uncertain is whether or not new dosage regimes are patentable under New Zealand law, as a method of using a substance or composition for treatment. The Assistant Commissioner of the Intellectual Property Office of New Zealand (IPONZ) in *Abbott*

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<sup>187</sup> S 9.

<sup>188</sup> Intellectual Property Office of New Zealand *New Zealand Intellectual Property Practice Notes: 1974-1998* (Ministry of Economic Development, April 2003) at 73.

<sup>189</sup> *Pharmaceutical Management Agency Ltd v Commissioner of Patents* [2000] 2 NZLR 529 at [64].

<sup>190</sup> At [53].

<sup>191</sup> At [54].

<sup>192</sup> At [26].

<sup>193</sup> *Pfizer Inc v Commissioner of Patents* [2005] 1 NZLR 362 at [63]-[64].

*Laboratories*<sup>194</sup> approved the UK case of *Bristol-Myers Squibb*,<sup>195</sup> which excluded from patentability new and inventive dosage regimes of a known medicament. However, the Assistant Commissioner in the later decision of *Merck & Co Inc*<sup>196</sup> followed the precedent set by the EPO (Technical Board of Appeal) in *Genentech Inc*,<sup>197</sup> which extended the scope of Swiss-type claims to cases where the novelty lies in the dose or manner of administration. The rationalisation for that extension was that the invention sought to achieve the most effective way to administer (use) a known composition, thereby directing itself to potentially patentable subject matter rather than method for treatment.<sup>198</sup> A third IPONZ decision, *Genentech Inc and Washington University*, confirmed the approach taken by the Assistant Commissioner in *Merck & Co Inc*, noting international developments in this field.<sup>199</sup> The IPONZ decisions occurred prior to the introduction of s 16 in the Patents Act 2013, which did not address this issue, nor did the Court of Appeal in *Pfizer Inc v Commissioner of Patents*. It has been suggested that, in light of the later judicial and statutory exclusions, it is not for IPONZ to determine the matter.<sup>200</sup> It may therefore be said that, until the matter is raised in the appropriate forum, the position on dosage regimes remains uncertain in New Zealand.

Based on the above, it may be posited that there is little significant difference in the approaches taken towards patentable subject matter between the EU and New Zealand. The main difference lies in the interpretation of novelty, with respect to the extent to which a second use may fall within a method for treatment. However, recent IPONZ decisions indicate the persuasiveness of international approaches, in particular those taken by the EU and the UK. These approaches have directly influenced the New Zealand position on this issue. Whether or not New Zealand chooses to continue following these approaches in the future is a matter for judicial or parliamentary authorities to determine. In any event, a divergent approach taken towards patentability for dosage regimes would not carry significant effects. Given that both parties permit second use patents within their domestic regimes and only diverge as to whether a particular second use may fall within the exclusion of a method for treatment, it is unlikely that

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<sup>194</sup> *Abbott Laboratories* [2003] NZIPOPAT 16 (11 August 2003).

<sup>195</sup> *Bristol-Myers Squibb Co v Baker Norton Pharmaceuticals Inc* [2000] EWCA Civ 414.

<sup>196</sup> *Merck & Co Inc v Arrow Pharmaceuticals (NZ) Limited* [2006] NZIPOPAT 3 (31 January 2006).

<sup>197</sup> T 1020/03 (Method of administration of IGF-I/*Genentech Inc*) of 29 October 2004, ECLI:EP:BA:2004:T102003.

<sup>198</sup> At 41-45.

<sup>199</sup> *Genentech Inc and Washington University* [2007] NZIPOPAT 1 (23 January 2007).

<sup>200</sup> Susy Frankel "Lord Cooke and Patents: The Scope of "Invention" (2008) 39 VUWLR 73 at 93-94.

there will be any difficulty in the area of patentable subject matter going forward in the negotiations for an EU-NZ FTA.

## 2 *Regulatory protection: data and market exclusivity*

Data and market exclusivity are conferred in the EU by Regulation (EC) No 726/2004.<sup>201</sup> Article 14.11 of that Regulation provides that pharmaceutical products which have obtained market authorisation shall benefit from an eight-year period of data protection and a ten-year period of marketing protection. This means that, for a period of eight years after the granting of marketing authorisation, a generic manufacturer may not use the data submitted by the originator manufacturer in support of their application. At the end of this period, the generic manufacturer may use that data in support of their application; however, marketing authorisation may not be granted to that generic product for a further period of two years. Marketing protection may be extended by a further one year if, during the first eight years, the marketing authorisation holder obtains an authorisation for one or more new therapeutic indications which are held to bring a significant clinical benefit in comparison with existing therapies.<sup>202</sup> In total, a pharmaceutical product may benefit from an 11-year period of regulatory protection under art 14.11, following an ‘8+2+1’ structure.

The one-year extension provided in art 14.11 is reiterated in the fourth subparagraph of art 10.1 of Directive 2001/83/EC. In order to obtain an additional one-year period of market exclusivity under either article, it must be shown that there is one or more new therapeutic indications and the indication must bring a significant clinical benefit in comparison with existing therapies. The European Commission has interpreted ‘new therapeutic indications’ as referring to either diagnosis, prevention or treatment of a disease.<sup>203</sup> Within the indication, the target disease or condition must be clearly defined, distinguishing between treatment, prevention and diagnostic indications.<sup>204</sup> Indications may include, but are not limited to, a new target disease or new population for the same disease, different stages for severity of a disease, a change in combination therapy, or a change from treatment to prevention or diagnosis of a disease.<sup>205</sup>

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<sup>201</sup> Regulation (EC) No 726/2004, above n 133, art 14.11.

<sup>202</sup> Art 14.11.

<sup>203</sup> European Commission *Guidance on elements required to support the significant clinical benefit in comparison with existing therapies of a new therapeutic indication in order to benefit from an extended (11-year) marketing protection period* (November 2007) at 3.1.

<sup>204</sup> European Commission *Notice to Applicants: A Guideline on Summary of Product Characteristics* (October 2005) at 4.1.

<sup>205</sup> European Commission *Guidance on elements required to support the significant clinical benefit*, above n 203.

Any indication must be proven ‘new’ in comparison to the therapeutic indication already authorised.<sup>206</sup>

In satisfying the second element, it must be shown that there is a significant clinical benefit “in comparison with existing therapies”.<sup>207</sup> It is not enough to simply show that there is a benefit from the new indication. Existing therapies means satisfactory methods of diagnosis, prevention or treatment of the disease, and may include all authorised pharmaceutical products for that therapy as well as other non-pharmacological methods.<sup>208</sup> In order to establish a significant clinical benefit in comparison with existing therapies, scientific data obtained from comparative clinical studies should be provided.<sup>209</sup> Finally, the new therapeutic indication must show a significant clinical benefit. The European Commission has indicated that “demonstration of greater efficacy, improved safety, and more favourable pharmacokinetic properties resulting in demonstrable clinical advantages compared to existing methods” should be enough to satisfy this element.<sup>210</sup> It may also include significant clinical benefits based on a major contribution to patient care, such as a new mode or route of administration which makes self-administration possible or easier for a patient to undertake.<sup>211</sup>

It must be noted that authorisation for the new indication must be granted within the first eight years after the granting of market authorisation for the reference product in order for the manufacturer to obtain the additional one-year period of exclusivity.<sup>212</sup> This means that any new or additional benefits cannot be authorised retrospectively.

In addition to the ‘8+2+1’ structure, extensions to both data and market exclusivity are permitted in specific and limited circumstances. Data exclusivity may be extended for an additional one-year period under art 10.5 of Directive 2001/83/EC, where significant pre-clinical or clinical studies were carried out in relation to an application for a new indication for a well-established substance. In assessing new indication, the same criteria apply to that discussed above relating to new therapeutic indications with significant clinical benefits. The second element requires that “significant pre-clinical or clinical studies” were carried out. The determination of ‘significant’ is a matter for the competent national authorities. However, the

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<sup>206</sup> At 3.

<sup>207</sup> Regulation (EC) No 726/2004, above n 133, art 14.11.

<sup>208</sup> European Commission *Guidance on elements required to support the significant clinical benefit*, above n 203, at 3.2.

<sup>209</sup> At 3.3.

<sup>210</sup> At 3.3.

<sup>211</sup> At 3.3.3.

<sup>212</sup> Regulation (EC) No 726/2004, above n 133, art 14.11 and Directive 2001/83/EC, above n 170, art 10.1.4.

European Commission has noted that, in principle, the applicant ought to have conducted at minimum one clinical trial which is compared to a suitable comparator and has indicated why it ought to be viewed as a significant clinical or pre-clinical study.<sup>213</sup> It is important to note that the additional one-year period of protection is ‘non-cumulative’ under art 10.5. This suggests that it would operate as a stand-alone one-year period of data exclusivity in addition to the standard ‘8+2+1’ structure. This additional year of data exclusivity would only extend to the data concerning the new indication.

An extension to market exclusivity may also be granted in respect of a pharmaceutical product designated as an orphan medicinal product, where the application for marketing authorisation includes the results of studies conducted in compliance with an agreed paediatric investigation plan.<sup>214</sup> The justification for this extension is to provide an incentive for the development of pharmaceutical products targeting rare conditions or diseases within the paediatric population. While orphan drugs are expressly granted ten years of market exclusivity, a further two-year period of market exclusivity is granted where such products address the paediatric population in accordance with EU legislation. This period may, however, be reduced to six years if, after the first five years, it is shown that the orphan product is sufficiently profitable not to justify maintenance of market exclusivity.<sup>215</sup> Nevertheless, the total period of market exclusivity that may be granted for such products is 12 years.

Data exclusivity within New Zealand is provided for in s 23 of the Medicines Act 1981. Section 23B of that Act requires the Minister of Health to protect confidential information submitted in support of an innovative medicine application. The Minister is obliged to take reasonable steps to ensure that confidential supporting information is kept confidential to the Minister and must not use that information for the purpose of determining whether to grant any other application during the protected period. Section 23A defines ‘protected period’ as no less than five years after the submission of the innovative medicine application to the Minister. Where the Minister notifies his consent or refusal to consent to the distribution of the medicine contained in the innovative medicine application, a five-year period of data protection shall commence on the date of notification. In other words, data exclusivity is granted for a period of five years from the date of approval or non-approval of a pharmaceutical product. Exceptions

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<sup>213</sup> European Commission *Guidance on a new therapeutic indication for a well-established substance* (November 2007) at 3.

<sup>214</sup> Regulation (EC) No 1901/2006, above n 166, art 37.

<sup>215</sup> Regulation (EC) No 141/2000 of the European Parliament and of the Council of 16 December 1999 on orphan medicinal products [2000] OJ L 18/1, art 8.2.

to data protection are stipulated in s 23C, including disclosures or use of that confidential information with the consent of the applicant or where a disclosure is necessary to protect public health or safety.

Data exclusivity only applies to ‘innovative medicines’. Under s 23A this means a medicine which contains an active ingredient that has not been previously submitted for approval as an active ingredient of a medicine.<sup>216</sup> This interpretation excludes from data protection any data submitted in support of a marketing authorisation for a new indication or formulation, which includes a pharmaceutical product under a second use patent. On the one hand, this diminishes the incentive of originator manufacturers to market their product in New Zealand, while on the other hand it promotes the development of generic pharmaceutical products – which is in the best interests of New Zealand to do. It is important to note that the provision does not prevent the granting of patents or marketing authorisations for new indications or formulations; it merely prevents the protection of the data submitted in relation to the new indication or formulation.

As is clear from the above, there is a significant difference between the regulatory regime applied in the EU and that applied in New Zealand. Both the EU and New Zealand provide for a period of data exclusivity upon approval of the pharmaceutical product. Where they differ is the total period of protection, extensions and scope of the protection. Unlike the EU, New Zealand does not provide for market exclusivity. Rather, market exclusivity is only provided to the extent that the protection is consequently afforded under data exclusivity.

The limited scope or coverage offered under the New Zealand data exclusivity regime excludes from data protection a product which would ordinarily qualify for regulatory protection and extensions to either data or market exclusivity within the EU. The EU permits extensions in relation to new indications for a well-established substance or new indications claiming significant benefits. Neither extension would be granted data protection in New Zealand, let alone an extension, as they pertain to new indications for an existing product and therefore do not comply with the interpretation given to ‘innovative medicines’. The third permitted extension discussed above, orphan medicines which include studies under a paediatric investigation plan, is provided as an incentive or reward for research in that area. Unlike other permissible extensions, it is not granted as an extension for a new indication. In this case, the originator pharmaceutical product would benefit from five years of data exclusivity in New

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<sup>216</sup> Medicines Act 1981, s 23A, ‘innovative medicine application’.

Zealand; however, it would not benefit from any extension unless provided for in law. Unless the EU and New Zealand consider scope or coverage to be a matter for each party to determine themselves, the interpretation given to ‘innovative medicines’ may present a challenge which would need to be overcome in the course of negotiations.

The maximum term of regulatory protection in the EU is eleven years compared to New Zealand’s five-year period of data protection. This may also be an issue which the parties would need to overcome in the course of negotiations. In particular, the term of protection in conjunction with the lack of market exclusivity within New Zealand. Market exclusivity in New Zealand is only provided to the extent that the protection is consequently afforded under data exclusivity. While a generic manufacturer may submit an application for marketing authorisation during the term of data exclusivity, they may not rely on or base their application on the confidential information provided by the originator manufacturer. The cost involved in producing pharmaceutical products, however, provides little incentive for a generic manufacturer to conduct their own studies. As a result, a generic manufacturer may not submit an application for marketing authorisation until the expiry of the five-year data exclusivity term. When marketing authorisation is ultimately granted, however, is a procedural matter for the marketing authority. However, it may be less than the two years of market exclusivity provided for by the EU. Based on this, it is likely that the length of protection will be an issue for the parties to overcome in the course of negotiations, for both data and market exclusivity.

#### *D Summary of Chapter: Determination of Challenges and Difficulties Going Forth in the Negotiations for an EU-NZ FTA*

Based on the preceding sections of this chapter, it is clear that there are many differences in the TRIPS-plus protections relating to pharmaceuticals between CETA, the TPP Agreement and the CPTPP. While many of these differences may be described as negligible or having limited effect, the same does not hold true for all. The purpose of this section is to determine any challenges or difficulties arising from those differences that would need to be overcome during the course of negotiations.

##### *1 Patent protection*

###### *(a) Patent term: extension/restoration*

Both CETA and the TPP Agreement mandate the implementation of patent term extension/restoration schemes. CETA prescribes a period of *sui generis* protection of between

two to five years, with the possibility of an extension, to be afforded at the request of the patent holder. This protection takes effect at the end of the patent term and confers on the patent holder protection for the product covered by the marketing authorisation and any use of that product that has been authorised prior to expiration of the *sui generis* protection. While the scope of *sui generis* protection afforded under CETA is broad, it does not necessarily follow that a Party may not limit the scope in its domestic law. CETA provides that the appropriate method of implementation is for each party to determine, thereby permitting flexibility to the interpretation and implementation of the obligations under that Agreement.

In comparison, the TPP Agreement prescribes two systems of patent term extension by distinguishing between the granting of a patent and the granting of marketing authorisation. The first grants a period of patent term adjustment where there has been an unreasonable delay in the issuance of the patent of a period of more than five years, while the second grants a period of patent term adjustment or, alternatively, *sui generis* protection for unreasonable curtailment of the effective patent term as a result of the marketing authorisation process. The reason for this distinction could be in recognition that the two processes are separate from each other and that a delay in one process does not necessarily mean that there is a corresponding delay in the other process. In this respect, an applicant for patent term extension/restoration may only claim for the loss they have actually suffered.

There are multiple differences between the provisions relating to patent term extension/restoration in CETA and the TPP Agreement. However, it does not mean that the two schemes are mutually exclusive. The reason for this is that both agreements offer a significant degree of flexibility to the Parties, so that they may be reconciled. Therefore, the wide scope of CETA could, to an extent, be limited by the Parties to unreasonable delays in the patent process or unreasonable curtailments of the effective patent term as a result of the marketing authorisation process, as requested by the TPP Agreement. Conversely, the period of adjustment afforded under the TPP Agreement could be limited by the parties to two to five years, like under CETA. Whether this limitation would apply to each of the two forms of patent term adjustment separately, or would apply in combination, would be a matter for each party to the TPP Agreement to determine for themselves. In this respect, the parties may be able to achieve a significant level of consistency between their domestic positions and the agreements.

With that being said, the provisions relating to patent term adjustment were suspended under the CPTPP and are no longer applicable as good law. The implication is that legislation enacted



by New Zealand in order to comply with its obligations under the TPP Agreement has not come into force and is unlikely to do so. The domestic situation is at present that New Zealand does not permit patent term extension. This is in direct contradiction to the EU, which provides a *sui generis* scheme for patent term restoration very similar to that under CETA. Given the high degree of similarity between the EU domestic legal position and the *sui generis* protection afforded under CETA, it may be inferred that patent term extension/restoration is an area of significant interest to the EU and that its inclusion within an EU-NZ FTA will be a priority. The challenge for negotiators during the course of negotiations will, therefore, be in determining whether New Zealand *should* enact a patent term extension/restoration scheme and, if so, to what extent.

(b) Patent linkage

As identified above, the most significant difference between the patent linkage provisions in CETA and those in the CPTPP is that the CPTPP obliges parties to adopt a patent linkage system while CETA does not. Rather, CETA recognises that some parties may permit such a system without obliging other parties to adopt one. That said, the preferred patent linkage system in the CPTPP would see the formation of a notification system which would allow patent holders to seek remedies prior to the granting of marketing authorisation, rather than a system which would preclude the granting of marketing authorisation where there is an applicable patent. Of the two systems, the notification system carries the least impact and, for many parties, may be implemented with little amendment to domestic laws. In this respect, it could be argued that there is very little practical difference between a provision that recognises a party's patent linkage system and a provision that requires very little amendment to a party's domestic law in order to be compliant.

Similarly, differences relating to patent linkage within each Party's domestic legal system are not significant enough to present a challenge for the Parties. The EU does not permit patent linkage in its legal system. It may be inferred that it was for this reason that patent linkage was recognised but not mandated in CETA. New Zealand, on the other hand, is bound to implement a patent linkage system as part of its obligations under the CPTPP. This requires, at the minimum, the implementation of a system which would allow the patent holder to be notified upon the submission of an application for marketing authorisation of a generic product. As discussed above, this system does not oblige parties to *provide* notification, merely to provide a system which would *allow for* notification. This suggests a very low threshold must be met

in order for patent linkage mechanisms to be deemed acceptable. In consideration of this low threshold, New Zealand holds the understanding that the current legal framework provides adequate patent linkage, therefore no legal change is necessary to be compliant with their obligation.

While there are literal differences between the respective obligations under CETA and the CPTPP, an analysis of those provisions indicates that the practical effect of those differences is very limited. At most, given the inclusion of the patent linkage provision in CETA in order to uphold and comply with Canada's domestic situation, a similar provision relating to equal treatment of litigants could be included within an EU-NZ FTA. With that being said, the notification system that New Zealand is obliged to implement does not give rise to issues relating to equal treatment of litigants, unlike the situation in Canada.<sup>217</sup> At any rate, New Zealand upholds the rule of law, including equality before the law, so the inclusion of such a provision would be neither controversial nor widely disputed. On this basis, it may be concluded that the inclusion of provisions similar to those discussed relating to patent linkage within an EU-NZ FTA would not pose any significant challenge or difficulty for the parties during the course of negotiations.

(c) Patentable subject matter: second use patents

In respect of patentable subject matter in general, there is no significant difference between the provisions of the TRIPS Agreement, CETA and the CPTPP. The TRIPS Agreement and the TPP Agreement (as incorporated into the CPTPP) both expressly define what is recognised as patentable subject matter, broadly being any invention which is new, involves an inventive step and is capable of industrial application. CETA sets out no precise definition but does provide that the provisions therein complement the rights and obligations between the parties under the TRIPS Agreement. While those terms are left to the interpretation of each individual party, the TPP Agreement does provide some clarity or guidance on what factors ought to be considered in determining each step.

The TPP Agreement goes beyond the TRIPS Agreement by incorporating a provision on second use patents. Rather than oblige parties to implement protection for second uses, the TPP Agreement instead requires that at least one of three forms of second use qualify for protection in the Parties' domestic law. This may be interpreted to mean that all parties to that Agreement

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<sup>217</sup> Note that in Canada only the generic manufacturer may appeal an unfavourable decision. See above n 123.

already provide protection for second uses, therefore, the intention behind that provision is to lock-in existing policies so that they may not be reversed or amended in a way to limit their endorsement. This provision was suspended under the CPTPP, the effect being that each Party retains the flexibility to determine the issue of second use patents.

Similarly, there is little significant difference between the EU and New Zealand in the domestic legislative implementation of patentable subject matter. Each Party applies the same three elements in the determination of what is patentable in a manner consistent with their respective international obligations. Where the main difference lies is in the interpretation of those elements. Of particular interest is the element ‘new’, which both the EU and New Zealand allowed to expand so as to include second uses of known substances. Crucially, it is the use of the known substance in the treatment of a disease rather than the method of treatment itself that is patentable. Irrespective of this, the EU includes new dosage regimes within the definition of second use, where it would otherwise have been treated as a method of treatment. The position in New Zealand remains uncertain as this issue has not yet come before the courts, although IPONZ decisions indicate it could go either way.

With that being said, barring treaty definition, interpretation is a domestic matter. This is reflected within the international agreements, which provide flexibility to parties on how their obligations are to be implemented within their domestic law. In addition, the suspension of the provision on second use patents from the CPTPP means that there is no practical difference between CETA and the CPTPP with respect to patentable subject matter. Even had that provision not been suspended, its inclusion would not have resulted in any significant difference between the agreements as it merely sought confirmation of the existence of second use within the domestic legal system rather than imposing it. As New Zealand already protects second uses, it would not have made a difference to its domestic position. On this basis, it may be concluded that the difference in interpretation is not of a nature significant enough to pose any challenge or difficulty to the EU and New Zealand in the course of their negotiations.

## *2 Regulatory protection: data and market exclusivity*

In accordance with their obligations under the TRIPS Agreement, both CETA and the TPP Agreement require parties to implement regulatory protection in respect of the protection of undisclosed test or clinical data submitted to authorities in order to gain marketing authorisation for a new pharmaceutical product. Both agreements go above those obligations by requiring parties to implement a minimum period of protection during which time a generic manufacturer

of a product may not use or rely on that undisclosed data with respect to authorisation for its own product. Under CETA, that minimum term is six years. In addition, CETA provides a period of market exclusivity, which applies for an additional two years after the expiry of the period of data protection. The purpose of this is to prevent generic manufacturers from marketing their product for an additional two years, during which time they may now use the data in order to obtain marketing authorisation without being able to place their product on the market.

In comparison, the TPP Agreement provides for a minimum period of five years protection during which time a generic manufacturer may not market their similar product. There is no obligation to protect such data against use or reliance by a generic manufacturer in obtaining marketing authorisation, although the parties do remain bound by their general obligations in respect of disclosure under the TRIPS Agreement. Despite the omission of a data exclusivity scheme in the TPP Agreement, the practical effect resulting from the schemes of both agreements is identical if the overall intention of the Parties is to prevent the access onto the market of a generic product for a specified period of time. Whether or not a generic manufacturer is permitted to use or rely upon the originator's data, they still may not market their product under either agreement until the expiry of the specified period of time. In this respect, the overall purpose is achieved, although the method in achieving it is not. The main difference is therefore the length of time which the protection is afforded for, which is dependent upon the domestic regimes of the Parties and their willingness to commit to anything further.

Similar to the provisions relating to patent term extension/restoration, the provisions relating to the protection of undisclosed data under the TPP Agreement have also been suspended and are consequently not applicable as good law. Irrespective of this, New Zealand already protects undisclosed data within its domestic law, by providing a five-year period of data exclusivity. In comparison, the EU envisions an '8+2+1' structure, providing for periods of both data and market exclusivity, in addition to a one-year extension in certain cases. The lack of market protection afforded by New Zealand coupled with the shorter period of data protection would likely present a challenge that the Parties would need to address in the course of negotiations. In addition, the data protection afforded by New Zealand only applies to innovative medicines. This significantly limits the scope or coverage as the interpretation for innovative medicines excludes new indications or formulations, thereby only protecting first references to an active ingredient. In other words, data relating to second use patents is precluded from protection,

whereas it may receive protection under EU law. While interpretation is a domestic matter, the limited scope may be an issue the parties may wish to address.

## *IV Geographical Indications*

### *A General Introduction*

The following chapter on GIs shall be broken into three sections. The first section shall provide a comparative interpretative analysis of TRIPS-plus protections within CETA, the TPP Agreement and the CPTPP, with the TRIPS Agreement providing a baseline for comparison. This analysis shall be conducted in accordance with arts 31 and 32 of the VCLT. The second section shall provide a comparative interpretative analysis of EU and New Zealand domestic law in order to ascertain the position of the Parties. Recourse will be had to archival materials, including government documents and position papers, in conducting this analysis. The third section shall pull together the main findings of this chapter to identify any challenges or difficulties which may arise and therefore need to be overcome during the course of negotiations.

### *B Interpretation and Comparative Analysis of TRIPS-plus Protections: TRIPS Agreement, CETA, TPP Agreement and CPTPP*

TRIPS-plus protection for GIs can broadly be described as relating to the extent to which protection is afforded to any given product or product class. Unlike the protection of pharmaceuticals, TRIPS-plus protection of GIs is not multi-faceted. The intention is to extend the protection conferred under the TRIPS Agreement to product classes other than those specified therein, and to broaden the scope of protection so as to afford more exclusive rights in respect of the use of the GI. It must be noted at the outset that the TPP Agreement and consequently the CPTPP do not provide for the specific protection of GIs. Neither agreement may therefore be said to be TRIPS-plus in this respect. In those agreements, emphasis is placed on the protection of distinctive signs under trade mark regimes instead. For this reason, a comparative interpretative analysis of TRIPS-plus protections between those agreements and CETA is not possible. However, a discussion of the differences between the agreements shall ensue in order to understand the different approaches taken by the Parties and what this may mean going forwards in the negotiations.

## 1 *Legal protection of geographical indications*

Article 22.2 of the TRIPS Agreement obliges parties to provide for the legal protection of GIs, by providing the following:

In respect of geographical indications, Members shall provide the legal means for interested parties to prevent:

- (a) the use of any means in the designation or presentation of a good that indicates or suggests that the good in question originates in a geographical area other than the true place of origin in a manner which misleads the public as to the geographical origin of the good;
- (b) any use which constitutes an act of unfair competition within the meaning of Article 10bis of the Paris Convention (1967).

The TRIPS Agreement does not require Members to protect a given GI of any Member. Rather, it obliges Members to implement a system whereby any interested party may legally prevent either of the situations in (a) or (b). As the TRIPS Agreement does not specify the particular system to be implemented, this is left for each Member to determine for themselves.<sup>218</sup>

Under art 22.2(a), a Member may prevent, in respect of a GI, the use of any means in the designation or presentation of a good that is untrue as to geographical origin and where it is misleading. The term ‘any means’ suggests that this would encompass more than the mere use of the indication name, including anything that would identify the good as coming from that region. Similarly, the reference to ‘presentation’ of a good would include a particular packaging style, including the use of colours and images indicative of a particular geographical location.<sup>219</sup> The use of such characteristics must suggest that the good comes from a location other than its true geographical origin and must be done in a manner that misleads. This final element of public misleading emphasises consumer protection to, arguably, the detriment of the goodwill or reputation of the GI.

As an example, the use of the term ‘Dutch’ coupled with the image of a Dutch flag on the front packaging of ‘Gouda Holland’ cheese would suggest that the true geographical origin is the region surrounding Gouda in the Netherlands. However, if this is accompanied with the terms

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<sup>218</sup> TRIPS Agreement, above n 3, art 1.1.

<sup>219</sup> For a further discussion on the protection against misleading use, see generally Peter-Tobias Stoll, Jan Busche and Katrin Arend (eds) *WTO – Trade-Related Aspects of Intellectual Property Rights* (2009, Martinus Nijhoff Publishers, Leiden) at 396.

‘style’ or ‘type’ and its true geographical origin is stated on the back packaging, it cannot reasonably be said that the use of geographically unique terms have been used in a manner which misleads the public as to the true origin of the good. The requirement of public misleading adds a hurdle to the protection of a GI, rather than focusing on the dilution in value or reputation which occurs irrespective of actual misleading. In balancing interests, the TRIPS Agreement therefore strikes a balance in favour of consumer protection.

A Member may also prevent the use of a name which constitutes unfair competition under art 22.2(b), which includes use which is liable to mislead the public.<sup>220</sup> While the standard in art 22.2(a) is that the use ‘misleads’, here the standard is that the use is ‘liable to mislead’. This provides a lower standard than that used in art 22.2(a) and may be easier for a right holder to prove. In addition to the general protection afforded to GIs under art 22, the TRIPS Agreement also provides additional protection for GIs for wines and spirits. Article 23.1 obliges Members to provide the legal means for interested parties to prevent the use of a GI identifying wines and spirits for those wines and spirits not originating in the place indicated by the GI in question,

... even where the true origin of the goods is indicated or the geographical indication is used in translation or accompanied by expressions such as “kind”, “type”, “style”, “imitation”, or the like.<sup>221</sup>

A number of elements arise under this provision. First, protection may be afforded to a product even where the true origin is indicated or the product is distinguished from the GI by use of accompanying terms. This provides a much higher standard of protection to a GI than that under art 22.2(a) as it prevents the use of the GI by anyone other than those whose products fully comply with the terms of the GI. Second, it is irrelevant whether there is an element of public misleading. Article 23.1 omits any reference to misleading and instead focuses on the objective use. In so doing, it shifts the focus of GI protection from consumer protection to dilution in value and reputation through misappropriated use. In this respect, the additional protection for wines and spirits seeks to provide stronger protection in favour of the right holder.

A third element limits or tempers the scope of art 23.1 as the provision “prevent[s] use of a geographical indication”. This means that the GI itself must be used in relation to the product;

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<sup>220</sup> Paris Convention, above n 13, art 10bis(3).

<sup>221</sup> Footnote omitted.



it is not enough to show that it was partially used or that a reasonable person would infer that the product is the same as one which references the GI. The implication is that a sparkling wine labelled, for example, ‘Vin de Bordeaux’ would not fall within art 23.1 as there is no use of the protected GI. If the label were to state ‘French-style Crémant de Bordeaux’, on the other hand, this would fall within art 23(1) as the GI has been used, even though it is accompanied by the term ‘French-style’. This limited scope must be compared to the scope under art 22.2(a) which prevents, in respect of GIs, “the *use of any means in the designation or presentation of any good*”.<sup>222</sup> This encompasses more than the use of the GI itself and would include use of any characteristics which would indicate or suggest that the product originates in a place other than its true place of origin. In other words, art 22(a) offers a wider scope.

CETA goes beyond the TRIPS Agreement in respect of legal protection for GIs by, first, imposing stronger protection than that afforded under the TRIPS Agreement and by, second, listing particular GIs where protection is mandatory within the domestic legal systems of both parties to that Agreement.

Article 20.19 of CETA sets out the legal protection to be afforded to listed geographical indications contained in annex 20-A of that agreement. Under art 20.19.1, it is mandatory for each Party to protect those listed indications according to the level of protection set out in art 20.19. Annex 20-A lists 143 EU GIs which Canada has agreed to protect within its domestic legal system. These cover food and drink products from multiple regions across the EU and consist of various product classes including cheeses, fresh and dry-cured meats, beer and hops, and oils and vinegars.

Of importance, wines and spirits are not included within annex 20-A. The reason for this is that specified GIs pertaining to wines and spirits of both Parties are already protected within each other’s domestic legal system, by virtue of the 2003 Wines and Spirit Drinks Agreement.<sup>223</sup> Under that agreement, the names listed therein are officially recognised and protected as a GI within the meaning of art 22.1 of the TRIPS Agreement and are eligible for protection within both parties.<sup>224</sup> Although the 2003 Wines and Spirit Drinks Agreement was enacted prior to CETA, it has been incorporated and made part of that Agreement under art 30.8.5 of CETA and is therefore relevant to this thesis.

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<sup>222</sup> Emphasis added.

<sup>223</sup> 2003 Wines and Spirit Drinks Agreement, above n 82.

<sup>224</sup> Arts 10.1, 11.1, 14.1 and 15.1.

The TRIPS Agreement does not require a Member to protect any given GI. Rather, Members are obliged to provide a system so that interested parties may prevent the use of the GI. Therefore, the listing of specified GIs and imposing mandatory protection of those terms is above and beyond what the TRIPS Agreement requires. In this respect, CETA may be described as proactive. In addition, the imposition of mandatory protection for listed GI terms shifts the burden for protecting an interest from the interested party (GI holder) to the state. Provided that a producer complies with the requirements of a GI in order to obtain GI status in his home country, his product will automatically be protected in the other party by virtue of that name being a listed product under CETA. This eliminates the burden of actively seeking to have his separate legal interest upheld. This shifting of burdens does, however, only apply to products listed in annex 20-A or within the 2003 Wines and Spirit Drinks Agreement. All other GIs not specifically listed would still be required to seek protection in the other party.

Article 20.19.2 incorporates the general protection afforded to GIs under art 22.1 of the TRIPS Agreement and is near identical in wording. The interpretation provided in respect of art 22.1 is therefore also applicable to art 20.19.2 of CETA. Article 20.19.2(a) of CETA, on the other hand, affords specific protection to the GIs listed in annex 20-A, which is above and beyond that afforded by the TRIPS Agreement. Article 20.19.2(a) provides:

Each Party shall provide the legal means for interested parties to prevent:

- (a) the use of a geographical indication of the other Party listed in Annex 20-A for a product that falls within the product class specified in Annex 20-A for that geographical indication and that either:
  - (i) does not originate in the place of origin specified in Annex 20-A for that geographical indication; or
  - (ii) does originate in the place of origin specified in Annex 20-A for the geographical indication but was not produced or manufactured in accordance with the laws and regulations of that other Party that would apply if the product were for consumption in the other Party;

A number of elements arise within that provision. First, and similarly to art 23.1 of the TRIPS Agreement, art 20.19.2(a) “prevent[s] the use of a geographical indication”. Again, this means that the GI itself must be used in relation to the product; it is not enough to show partial use or that a reasonable person would infer that the product is in fact one covered by a GI. One particular issue that arises from this limitation relates to the use of GIs which are registered

under compound terms or names. The use of one part of that name under art 20.19.2(a) is not considered use of the GI as a whole and is therefore permissible. For example, a product sold under the name ‘Dutch Gouda’ or ‘Gouda’ is acceptable as it constitutes only partial use of the GI.<sup>225</sup> However, a product sold under the name ‘Gouda Holland’, which is a registered GI and is listed within annex 20-A, would not be acceptable if it was not manufactured in compliance with the stipulations of the GI. A similar issue would arise, as an example, with the use of Edam (protected under the GI ‘Edam Holland’) or Manchego (protected under the GI ‘Queso Manchego’).

Second, the use of the GI may only be prevented for a product that falls within the specified product class in annex 20-A. The implication is that the use of a GI for a product falling within a *different* product class to that specified is not preventable. The practical effect of this is somewhat diminished by the common knowledge of what products the GI actually covers. For example, a beer labelled ‘Gouda Holland’ is unlikely to create confusion or diminish the value of the GI as it is common knowledge that Gouda Holland refers to cheese, not beer.

On the other hand, a beer labelled ‘Žatecký Chmel’ (Saaz hops) may create confusion or may diminish the value of the GI as it is well known that hops are an essential ingredient in most beers, even if it is stated on the label that a different variety of hops was used than that which is covered by the GI. An argument could be made that, as beer is a product created through the use of hops, the use of the GI for the name of the beer is in fact a representation of the variety of hops used in creating that finished product. The use of the GI would, therefore, refer to the hops used to create that product rather than the product itself. On this basis, use of that GI in relation to a beer which is not created with the variety of hops covered by the GI may be preventable. A strict interpretation of art 20.19.2(a), however, would suggest otherwise, as the use is clearly in relation to a name of beer rather than the hops used to create that beer, and therefore a different product class. Irrespectively, an argument could be raised under fair trading laws instead, claiming deceit or misrepresentation in trade.

Finally, in order for use to be preventable, the product must either not originate in the place specified in annex 20-A for that GI or originate in that place but not be produced in accordance

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<sup>225</sup> Note that ‘Gouda Holland’ is a Protected Geographical Indication (PGI) within the EU and may only be used in compliance with the strict requirements set by cheesemakers and the Dutch Dairy Association. All other forms of the generic term ‘Gouda’ are permitted provided products are not labelled ‘Gouda Holland’. See Government of the Netherlands “Dutch cheeses Edam Holland and Gouda Holland granted protected status” (08 October 2010) <<https://www.government.nl/latest/news/2010/10/08/dutch-cheeses-edam-holland-and-gouda-holland-granted-protected-status>>.

with the applicable laws and regulations of the relevant party. The former is easy enough to identify by ensuring that the true origin is indicated on product labels. So, for example, a cheese labelled ‘Roquefort’ with a place of origin specified as Germany would be in breach of art 20.19.2(a) as the specified place of origin for that GI is France. The latter is more difficult in identifying as the specified place of origin for all products in annex 20-A refers simply to the country of origin. Many GIs are region-specific. A product may correctly indicate the place of origin as specified in annex 20-A; however, it is not produced in accordance with the laws of that country. For example, the specified place of origin of the GI ‘Parmigiano Reggiano’ is Italy, whereas the concise defined geographical area comprises the territories of the Provinces of Bologna to the left of the Reno River, Mantua to the right of the River Po, Modena, Parma and Reggio in the Emilia Region.<sup>226</sup> A cheese labelled ‘Parmigiano Reggiano’ and produced in Sicily would therefore not be produced in accordance with the laws of Italy relating to that specific GI, even if the label specifies its place of origin is Italy.

Article 20.19.3 continues on by stating that the protection offered in art 20.19.2(a) shall be provided:

... even where the true origin of the product is indicated or the geographical indication is used in translation or accompanied by expressions such as “kind”, “type”, “style”, “imitation” or the like.

The above provision is identical to the wording used in art 23.1 of the TRIPS Agreement in relation to additional protection afforded to wines and spirits. The interpretation in relation to that provision is, therefore, also applicable to art 20.19.3.<sup>227</sup> The only difference between the two provisions is the subject matter. Whereas art 23.1 of TRIPS applies only to GIs for wines and spirits, art 20.19.3 applies to the GIs specified in annex 20-A of CETA. It is important to note that, under art 20.21 of CETA, the use of a couple of specified GIs is permitted when the use of those terms is accompanied by the expressions listed in art 20.19.3.<sup>228</sup> These GIs may be considered as contested between the Parties and their use is only permitted in combination with a legible and visible indication of the geographical origin of the product concerned.<sup>229</sup>

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<sup>226</sup> European Commission *Publication of an amendment application pursuant to Article 6(2) of Council Regulation (EC) No 510/2006 on the protection of geographical indications and designations of origin for agricultural products and foodstuffs* (16 April 2009) OJ C 87/1 at 18.

<sup>227</sup> See also CETA, above n 5, art 29.17.

<sup>228</sup> Being those GIs indicated with a single asterisk in annex 20-A: Feta, Munster, Asiago, Fontina, Gorgonzola.

<sup>229</sup> CETA, above n 5, art 20.21.1.

While there are many similarities in respect of the provisions affording protection to GIs between the TRIPS Agreement and CETA, it is the higher standard of protection for GIs in conjunction with the mandatory protection of specified GIs in annex 20-A that makes the protections in CETA TRIPS-plus. While the TRIPS Agreement provides a higher standard of protection to wines and spirits as opposed to all other GIs, CETA provides a higher standard of protection to a broader variety of product classes, giving it a more expansive range. This is in addition to those products listed within the 2003 Wines and Spirit Drinks Agreement, which are incorporated into CETA. Furthermore, the specification of GIs to which the provision applies provides a concise and definitive list of those GIs which are to receive mandatory protection through the prevention of their use. This includes their use in conjunction with any accompanying terms or translations. While the TRIPS Agreement provides similar protection for wines and spirit drinks, it does not prescribe protection for specific GIs or for products outside of those two product classes. In this respect, the provisions in CETA are proactive as they force the Parties to protect those specified terms from unauthorised use, thereby providing stronger protection for the specified GIs.

As mentioned above, the CPTPP, in comparison, does not require parties to protect a given GI, nor does it specify the extent to which a given GI is to be protected. Rather than require protection, parties to the CPTPP chose instead to specify the means through which protection may be afforded, recognising that GIs may be protected through a trade mark or *sui generis* system or some other legal means.<sup>230</sup> The remainder of the section on GIs within the CPTPP addresses administrative procedures pertaining to the protection or recognition of GIs, including procedures relating to the opposition of registration of a GI. Such procedures also apply to GIs recognised or protected pursuant to an international agreement concluded after the conclusion of the CPTPP. Consequently, the provisions relating to GIs can to a large extent be described as reactive, as opposed to the proactivity mandated under CETA.

Irrespectively, Parties to the CPTPP remain bound to the TRIPS Agreement, so the failure to specify protection within the CPTPP does not detract from the general obligation to provide a system in order for interested parties to prevent usage, in accordance with art 22.2 of the TRIPS Agreement.<sup>231</sup> It does, however, indicate the intention of the parties to provide no additional

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<sup>230</sup> TPP Agreement, above n 7, art 18.30.

<sup>231</sup> Note that art 18.36.4 of the TPP Agreement stipulates that provisions relating to objection and cancellation procedures do not apply to GIs for wines and spirits or applications for those indications. This is due to their specific protection within art 23 of the TRIPS Agreement.

protection than what is required under the TRIPS Agreement, therefore the CPTPP cannot be said to be TRIPS-plus.

## 2 *Differing approaches: the relationship between geographical indications and trade marks*

It is well documented that in many jurisdictions, GIs are considered the same as or similar to a trade mark, so that the protection afforded to a trade mark may also similarly apply to a GI. This is the case particularly in the US and Canada, where GIs are protected by trade mark as certification marks. In comparison, the EU protects GIs under their own unique IPR. The broad argument raised in favour of this latter approach is that GIs are inherently different from trade marks. While multiple producers across a given geographical region may apply for the same GI for the same product, a trade mark is held by one producer, irrespective of geographical location. The focus of each is also inherently different, with trade marks focusing on brand and consumer protection, and GIs on the economic value of a name. While the EU succeeded in incorporating protection for GIs within the TRIPS Agreement, many countries have been unwilling to offer more protection than required by TRIPS. This has been reflected within trade agreements, as is apparent between CETA and the CPTPP.

The CPTPP may be said to place primacy on trade marks over GIs, the reason being that GIs are considered sufficiently protected under the trade mark system. Hence why there is no need to protect them by another method such as that required under the TRIPS Agreement or CETA. This point is established in art 18.19 of the TPP Agreement which states that “[e]ach Party shall also provide that signs that may serve as geographical indications are capable of protection under its trademark system”. Of notability is the reference to “signs that may serve as geographical indications”. The focus here is not on the GI itself but the sign which indicates the existence of a GI and which may be capable of obtaining trade mark protection. It must be noted that art 18.19 does impliedly distinguish GIs from trade marks by stating that such signs are capable of protection under the trade mark system. This indicates that GIs and trade marks are different, albeit that the protection afforded by trade marks is sufficient to also protect GIs.

The primacy of trade marks over GIs is further emphasised in art 18.20 which establishes the exclusive right for owners of registered trade marks to “prevent third parties that do not have the owner’s consent from using in the course of trade identical or similar signs, including subsequent geographical indications”. Permitting a trade mark owner to prevent use in the course of trade of identical or similar signs, whether or not that sign is subsequently protected

as a GI, indicates that the rights of the trade mark owner prevail to the detriment of others who use that sign without the trade mark owners' permission.

Despite the divergent approaches taken by the Parties, it does not necessarily follow that a GI will never be afforded protection under the CPTPP or similarly that a trade mark corresponding to a GI will never be afforded protection under CETA. Provisions exist within each Agreement that operate to resolve conflicts that are based upon the different approaches that may be taken to the protection of distinctive signs. For the most part, what matters is timing.

Article 18.20 grants the exclusive right for a trade mark holder to prevent the use of an identical or similar sign, *including subsequent geographical indications*, where such use is unauthorised. This may be interpreted as meaning that this provision applies to GIs where protection is sought after the signing or entry into force of the CPTPP and there is already an enforceable trade mark in existence. If this interpretation is correct, then this provision may arguably suggest that the exclusive right to prevent use does not apply where there is prior use or protection of a GI, only subsequent.

On the other hand, footnote 11 (Chapter 18) of the TPP Agreement states that, “[f]or greater certainty, the exclusive right in this Article applies to cases of unauthorised use of geographical indications”. An argument may be made that, if a GI is protected by a party, then its use is not unauthorised and it therefore does not fall within this provision, whether or not protection is subsequent. Additionally, if a party authorises protection for a GI irrespective of an existing trade mark, then the trade mark holder cannot be said to have the exclusive right to use of that sign. This interpretation would suggest that both trade mark and GI could co-exist irrespective of prior use or protection, provided that the GI is authorised by that party.

The validity of the exception for prior use is strengthened in art 18.32.1 which sets out obligations where a party to the CPTPP protects or recognises GIs through administrative procedures as opposed to trade marks. Where that is the case, art 18.32.1 requires the party to provide objection procedures and to refuse or otherwise not afford protection when certain grounds are met. Two of those grounds relate to trade marks and focus on the likelihood of the GI causing confusion with an established trade mark.<sup>232</sup> In both instances, the trade mark or its use in good faith pending application or registration is already in existence prior to protection being sought for a GI. Therefore, the basis for objecting to protection is pre-existing rights.

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<sup>232</sup> TPP Agreement, above n 7, art 18.32.1(a) and (b).

CETA requires the registration of a trade mark to be refused or invalidated where the trade mark contains or consists of a GI listed in annex 20-A.<sup>233</sup> This applies with respect to a product that falls within the product class specified in that annex and which does not originate in the specified place of origin.<sup>234</sup> Reference to product class may arguably be interpreted to mean that a trade mark registered in respect of a product falling within a *different* product class than that specified would remain valid. This would be consistent with the discussion in the above section relating to the use of a GI as per art 20.19.2(a) of CETA.

Irrespective, CETA similarly provides an exception in order to protect trade marks where there has been prior use of a GI.<sup>235</sup> This is applicable in respect of a GI used prior to the signing of CETA or, where the GI is later added to annex 20-A, prior to the date of inclusion. Of significance is that prior use occurs where a trade mark has been applied for or registered in good faith or where rights have been acquired through use in good faith.<sup>236</sup> The grounds for exempting prior use are near identical to those provided under art 18.32.1 of the TPP Agreement.

Based on the above it may be said that where there is a pre-existing right, the approach is to uphold that right. Nevertheless, in consideration of the approach taken within the TRIPS Agreement and CETA, and the contrasting approach taken within the CPTPP, it is arguable that the CPTPP evidences an attempt to ‘rollback’ the protections afforded under the TRIPS Agreement and agreements such as CETA. As the approach taken under the CPTPP is broadly reflective of the domestic approaches to GI protection within the Parties to that Agreement, the provisions may be seen as the Parties seeking to protect the status quo. The practical effect is to prevent or limit parties from protecting, thereby limiting the global expansion of GIs as their own unique IPR outside the realm of wines and spirits in accordance with the TRIPS Agreement. That said, exemptions are made for prior uses of a GI so that a party would not be bound to invalidate an existing GI simply by ratifying the CPTPP. The ancillary effect of this is arguably to reassure parties that conflicting protection of IPR will not render a party in violation of one trade agreement upon entry into another where the protection of distinctive signs is afforded by another mode.

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<sup>233</sup> CETA, above n 5, art 20.19.6.

<sup>234</sup> Art 20.19.6.

<sup>235</sup> Art 20.21.5.

<sup>236</sup> Art 20.21.5.



## C *Interpretation and Comparative Analysis of Domestic Law: European Union and New Zealand*

As previously stated, international trade agreements are the result of negotiation and as such may be seen as culminations of multiple interests across multiple parties. As interests are often diverse between negotiating parties, international trade agreements may not accurately reflect the domestic position of any given party. The aim of this section is therefore to provide a comparative interpretative analysis of EU and NZ domestic law relating to the protection of GIs in order to ascertain the respective positions of the Parties and to determine any challenges or differences between their respective laws.

The domestic legal approach taken towards GI protection significantly differs between the EU and New Zealand. Whereas the EU provides for a *sui generis* regime based upon product registration under EU quality schemes, New Zealand offers protection under a range of existing statutory and common law rules. Most of these rules have general application and do not specifically apply to GIs. In accordance with its obligations under the TRIPS Agreement,<sup>237</sup> a wine and spirits registrar has also been established, coming into force in July 2017. This permits the registration of GI names for applicable products, similar to the *sui generis* regime of the EU.

Due to the differing legal approaches, this section shall be divided into two parts. The first part shall interpret and compare the registration schemes of both the EU and New Zealand while the second part shall discuss the application of other existing legal rules in the absence of a specific registration scheme. It must be noted that a complete analysis of the registration schemes is not possible within the scope of this thesis. The analysis will therefore strictly focus on the protection of GIs and relevant exceptions thereto.

### 1 *Registration schemes for the protection of geographical indications*

#### (a) Identification of registration schemes

Protection of GIs within the EU is afforded in accordance with EU quality schemes, which protect the names of specific products which are linked to geographical origin in addition to traditional knowledge.<sup>238</sup> Products may be identified with a GI if they fall within any of the

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<sup>237</sup> TRIPS Agreement, above n 3, art 23.1.

<sup>238</sup> European Commission “Quality schemes explained” <[https://ec.europa.eu/info/food-farming-fisheries/food-safety-and-quality/certification/quality-labels/quality-schemes-explained\\_en](https://ec.europa.eu/info/food-farming-fisheries/food-safety-and-quality/certification/quality-labels/quality-schemes-explained_en)>.

following three predominant quality schemes: Protected Designation of Origin (PDO), Protected Geographical Indication (PGI) and Geographical Indication.<sup>239</sup> For the purposes of this thesis, reference to the broad term GI shall be understood as encompassing the above three schemes, unless otherwise stated.

The EU quality schemes PDO and PGI were established under Regulation (EU) No 1151/2012<sup>240</sup> in order to ensure uniform protection of specific names as IP and to provide consumers with clear information on the value-adding attributes associated with such names.<sup>241</sup> In accordance with art 5.1 of that Regulation, to be identified as a PDO a product must originate in a specific place, the quality or characteristics must be “essentially or exclusively due to a particular geographical environment with its inherent natural and human factors”, and all of the production steps must take place in the defined geographical area. Whereas in accordance with art 5.2 of that Regulation, to be identified as a PGI a product must originate in a specific place, the given quality, reputation or other characteristics must be essentially attributable to its geographical origin, and at least one of the production steps must take place in the defined geographical area. The main difference between the two relates to the strength of the relationship between the product and the specific geographical origin: where all aspects of the production, processing and preparation must occur in the specific region for a PDO, in comparison to the less stringent requirements regarding origin and production process for a PGI. A Geographical Indication, on the other hand, is almost identical to a PGI, but omits the requirement in respect of product steps.<sup>242</sup>

Only products which fall within particular product classes may apply for EU GI status, being wines (aromatised and other), spirit drinks and agricultural products and foodstuffs. Consequently, the protection afforded to GIs is granted under a complex legal framework which involves various pieces of legislation. Of relevance to this thesis are the following:

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<sup>239</sup> Note that a fourth quality scheme ‘Traditional Specialty Guaranteed’ exists to protect traditional aspects of a product against misuse or falsification, without being linked to a particular geographical location.

<sup>240</sup> Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs [2012] OJ L 343/1.

<sup>241</sup> Art 4.

<sup>242</sup> See Regulation (EC) No 110/2008 of the European Parliament and of the Council of 15 January 2008 on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks and repealing Council Regulation (EEC) No 1576/89 [2008] OJ L 39/16, art 15 and Regulation (EU) No 251/2014 of the European Parliament and of the Council of 26 February 2014 on the definition, description, presentation, labelling and the protection of geographical indications of aromatised wine products and repealing Council Regulation (EEC) No 1601/91 [2014] OJ L 84/14, art 2.3.

- For agricultural products and foodstuffs: Regulation (EU) No 1151/2012 of the European Parliament and of the Council of 21 November 2012 on quality schemes for agricultural products and foodstuffs;
- For wine: Regulation (EU) No 1308/2013 of the European Parliament and of the Council of 17 December 2013 establishing a common organisation of the markets in agricultural products and repealing Council Regulations (EEC) No 922/72, (EEC) No 234/79, (EC) No 1037/2001 and (EC) No 1234/2007;<sup>243</sup>
- For aromatised wine: Regulation (EU) No 251/2014 of the European Parliament and of the Council of 26 February 2014 on the definition, description, presentation, labelling and the protection of geographical indications of aromatised wine products and repealing Council Regulation (EEC) No 1601/91;<sup>244</sup>
- For spirit drinks: Regulation (EC) No 110/2008 of the European Parliament and of the Council of 15 January 2008 on the definition, description, presentation, labelling and the protection of geographical indications of spirit drinks and repealing Council Regulation (EEC) No 1576/89.<sup>245</sup>

Under Regulation (EU) No 1151/2012, agricultural products intended for human consumption may be protected by either a PDO or PGI.<sup>246</sup> This applies to all products listed in annex 1 of the TFEU, including cheeses and dry-cured meats. Similarly, under Regulation (EU) No 1308/2013, wine may be protected by either a PDO or a PGI.<sup>247</sup> Spirit drinks and aromatised wines, on the other hand, may apply for a Geographical Indication under Regulation (EC) No 110/2008 and Regulation (EU) No 251/2014 respectively.<sup>248</sup>

In accordance with its international obligations, New Zealand enacted the Geographical Indications (Wine and Spirits) Registration Act 2006,<sup>249</sup> which entered into force in July 2017. The purpose of that Act is to provide a suitable legal framework for the registration of GIs and to protect the interests of consumers by providing assurance that applicable products using a GI do originate in the territory, region or locality to which the registered GI relates.<sup>250</sup> A GI is defined under s 6(1) as “an indication that identifies a wine or spirit as originating in the

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<sup>243</sup> [2013] OJ L 347/671.

<sup>244</sup> See above n 242.

<sup>245</sup> See above n 242.

<sup>246</sup> Regulation (EU) No 1151/2012, above n 240, art 2.1.

<sup>247</sup> Regulation (EU) No 1308/2013, above n 243, art 103.1.

<sup>248</sup> Regulation (EC) No 110/2008, above n 242, art 15.1 and Regulation (EU) No 251/2014, above n 242, art 20.1.

<sup>249</sup> As amended by the Geographical Indications (Wines and Spirits) Registration Amendment Act 2016.

<sup>250</sup> Geographical Indications (Wines and Spirits) Registration Act 2006, s 3(a) and (c).

territory of a country, or a region or locality in that territory, where a given quality, or reputation, or other characteristic of the wine or spirit is essentially attributable to its geographical origin”. This definition includes both New Zealand and foreign GIs.<sup>251</sup> In order for a GI to be protected in New Zealand, it must be registered under s 8 of that Act.

As indicated above, the EU permits the granting of a GI to products within the product classes wines, spirit drinks and agricultural products and foodstuffs. In comparison, New Zealand only permits the granting of a GI by registration to products identified as wines and spirit drinks. Producers of a product in any other product class would need to avail themselves of the other legal protections offered in order to protect their name within New Zealand. Considering the emphasis placed by the EU on the availability of protection for a registered GI, this limited coverage will almost certainly be identified as an area of high importance during the course of negotiations for an EU-NZ FTA.

(b) Protection afforded to geographical indications

The protection afforded to GIs in the EU is broadly consistent across the different product classes and legislation.<sup>252</sup> To use as an example, art 13.1 of Regulation (EU) No 1151/2012 provides:

Registered names shall be protected against:

- (a) any direct or indirect commercial use of a registered name in respect of products not covered by the registration where those products are comparable to the products registered under that name or where using the name exploits the reputation of the protected name, including when those products are used as an ingredient;
- (b) any misuse, imitation or evocation, even if the true origin of the products or services is indicated or if the protected name is translated or accompanied by an expression such as ‘style’, ‘type’, ‘method’, ‘as produced in’, ‘imitation’ or similar, including when those products are used as an ingredient;
- (c) any other false or misleading indication as to the provenance, origin, nature or essential qualities of the product that is used on the inner or outer packaging, advertising material or documents relating to the product concerned, and the packing of the product in a container liable to convey a false impression as to its origin;

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<sup>251</sup> S 6(2) and (3).

<sup>252</sup> Compare Regulation (EU) No 1151/2012, above n 240, art 13; Regulation (EC) No 1308/2013, above n 243, art 103.2; Regulation (EU) No 251/2014, above n 242, art 20.2 and Regulation (EC) No 110/2008, above n 242, art 16.

(d) any other practice liable to mislead the consumer as to the true origin of the product.

A number of elements arise from the protection afforded to GIs. First, any direct or indirect use must be commercial. Any use that is not in the course of trade or business will not fall within art 13.1. Second, the use need not only be direct, but may also be indirect. Indirect use of a GI may include, but is not limited to, pictures of landscapes or familiar landmarks, heraldic signs, images of well-known persons<sup>253</sup> or trade dress<sup>254</sup>.<sup>255</sup> The reference to indirect use may also be broad enough to encompass uses accompanied by expressions indicated in art 13.1(b), in addition to packaging presentation as indicated in art 13.1(c), provided that the use is commercial. In any event, the indirect use must be associated with the GI to an extent sufficient to cause confusion with a comparable product or to affect the reputation of the GI.

Third, the use of accompanying expressions is prohibited, even where the true origin is stated or where their use would convey that they are not the true product. This corresponds to art 23.1 of the TRIPS Agreement and art 20.19.3 of CETA. What is noteworthy is the inclusion of the term ‘evocation’, which is not included within either of those agreements. This means that any use which invokes a feeling, memory or image of that GI is prohibited.<sup>256</sup> Such use may include a catchphrase, a particular style of font or combination of colours on the packaging. Finally, elements of both producer and consumer protection have been included within that provision. Both (a) and (b) focus primarily on the protection afforded to a GI, while (c) and (d) focus on misleading and deceptive conduct in relation to the true origin of a product. Despite the inclusion of elements relating to consumer protection, however, the emphasis is on the protection of the GI, as indicated by the commencing phrase “Registered names shall be protected against”.

Sections 21 to 25 of the Geographical Indications (Wine and Spirits) Registration Act provide for the protection of GIs by imposing restrictions on the use of registered GIs. Section 21 imposes restrictions on the use of a New Zealand registered GI for wine. That section provides

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<sup>253</sup> For example, the inclusion on a label for chocolates of an image of Mozart may indirectly indicate the origin as Austria, without explicitly stating the place of origin.

<sup>254</sup> For example, the use of the ‘Clavelin’ bottle may only be used by French wines bearing the PDOs Côte du Jura, Arbois, L’Etoile and Château Chalon. Commission Delegated Regulation (EU) No 2019/33 of 17 October 2018 supplementing Regulation (EU) No 1308/2013 of the European Parliament and of the Council as regards applications for protection of designations of origin, geographical indications and traditional terms in the wine sector, the objective procedure, restrictions of use, amendments to product specifications, cancellation of protection, and labelling and presentation [2019] OJ L 9/2, annex VII at 3.

<sup>255</sup> Albrecht Conrad “The Protection of Geographical Indications in the TRIPS Agreement” (1996) 86 *Trademark Rep* 11 at 11.

<sup>256</sup> English Oxford Living Dictionaries, above n 113, ‘evocation’.

that a person may use a New Zealand registered GI in trade in New Zealand in relation to wine only if at least 85% of the wine is obtained from grapes harvested in the place of geographical origin to which the GI relates, the remainder of the wine is obtained from grapes harvested in New Zealand, and the GI is used in accordance with its registration. Section 23 applies to the use of a New Zealand GI registered for spirits, providing that a person may use that GI in trade only if the spirit originated in the place of origin to which the GI relates, and its use is in accordance with its registration. Sections 22 and 24 apply identically and respectively to the use of foreign registered GIs for wines and spirits. Both sections provide that a person may use those GIs in trade in New Zealand only if the wine or spirit originated in the place or places of origin to which the foreign registered GI relates, and the GI is used in accordance with the scope of its protection in its country of origin, and with its registration in New Zealand.

Section 25 provides additional rules relating to restrictions on use. Under that section, the restrictions on use in accordance with ss 21–24 apply whether or not the true place of origin of the wine or spirit is indicated, the registered GI is used in translation, or the use of the registered GI is accompanied by the expressions ‘kind’, ‘type’, ‘style’, ‘imitation’ or any similar word or expression.

Significantly, the above five sections refer broadly to the ‘use’ of those GIs in trade, as opposed to “any direct or indirect commercial use of a registered name” under art 13.1(a) of regulation (EU) No 1151/2012. No interpretation for the term ‘use’ is provided within the Geographical Indications (Wine and Spirits) Registration Act. Furthermore, its dictionary definition provides little clarity, defining ‘use’ as ‘the action of using something or the state of being used for a purpose’.<sup>257</sup> While in a broad sense ‘use’ may encompass both direct and indirect forms, its interpretation must be done in a manner consistent with the context.

Under ss 21–24, “[a] person may use a [New Zealand/foreign] geographical indication”. Geographical indication is defined under s 6(1) as “an *indication* that identifies a wine or spirit as originating in the territory of a country, or a region or locality in that territory”.<sup>258</sup> More often than not it is the *name* of the GI, typically the place of origin, that indicates or is associated with that information. Indeed, the registration of a GI is done in accordance with the name of the GI. On this basis, the use of a GI would mean the name used to protect the particular product.

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<sup>257</sup> English Oxford Living Dictionaries, above n 113, ‘use’.

<sup>258</sup> Emphasis added.

This interpretation is consistent with art 13.1(a) of Regulation (EU) 1151/2012 in respect of protection against the use of registered names. The main difference between that provision and the restrictions on use under the Geographical Indications (Wine and Spirits) Registration Act is therefore the form of use. On the one hand, the purpose under s 3(d) of that Act is to facilitate, in a manner consistent with New Zealand's obligations under the TRIPS Agreement, the other purposes listed therein. This includes the protection of the interests of consumers of wines and spirits by providing assurance that a product using a GI originates in the true geographical place of origin.<sup>259</sup> It is arguable that, in achieving that purpose, use of a GI would extend to any means in the designation or presentation of a good in accordance with art 22.2(a) of the TRIPS Agreement – in other words, indirect use. On the other hand, the additional restrictions under s 25 of the Geographical Indications (Wine and Spirits) Registration Act suggest that actual or 'direct' use of the GI is required, in particular the use of expression accompanying the GI and the use of the GI in translation. Furthermore, a good faith reading of the provisions relating to restriction to use would prevent reading in provisions that are not expressly included. In the absence of express provision to the contrary, the term 'use' may be interpreted as meaning actual use of the name of the applicable GI.

It is clear from the above that the protection afforded under the Geographical Indications (Wine and Spirits) Registration Act only applies to actual use of the GI name, whether or not any of the additional protections in s 25 apply. This is in comparison to art 13.1 of Regulation (EU) No 1151/2012 which also protects against misleading and deceptive use. This protection is in addition to the broader protection granted under that Regulation with respect to unauthorised use of the registered name. Despite not specifically protecting against misleading or deceptive use within the Geographical Indications (Wine and Spirits) Registration Act, New Zealand law does still offer adequate protection under other legal instruments.<sup>260</sup> As the scope of other legal protection is wide enough to encompass protection similar to that provided under art 13.1(c) and (d) of Regulation (EU) No 1151/2012, it may be said that there is little significant difference between the domestic regimes of both New Zealand and the EU in that respect. The only significant difference with respect to the protection afforded to GIs is therefore in relation to the form of use.

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<sup>259</sup> Geographical Indications (Wine and Spirits) Registration Act 2006, s 3(c).

<sup>260</sup> See discussion below in relation to the Fair Trading Act 1986 and the tort of passing off.

(c) Exceptions to legal protection afforded to geographical indications

In addition to conferring protection under their respective registration regimes, both the EU and New Zealand also provide exceptions to that protection in limited circumstances. While exceptions to protection are not TRIPS-plus in nature and therefore were not discussed in the preceding section, their inclusion within the respective registration regimes indicates the extent to which protection is afforded by the Parties and therefore assists in understanding the positions of the Parties. For this reason, they shall be interpreted and compared here.

(i) Grandfathering/continuous use

None of the relevant EU legislation contains provisions on continuous use of a GI. The only exception is where there is a pre-existing trade mark. In that situation, provided that the trade mark had been applied for, registered or established by use in good faith before the date of protection of the GI in its country of origin, the trade mark may continue to be used and renewed irrespective of the GI, and provided that no grounds for invalidity or revocation exist.<sup>261</sup> A trade mark and GI may, therefore, exist alongside one another where there is a pre-existing trade mark.<sup>262</sup> This exception for a pre-existing trade mark is broadly consistent across the four relevant pieces of legislation and is consistent with the EU's obligations under art 20.21.5 of CETA.

Although it does not contain provisions for the continuous use of a GI where there is no pre-existing trademark, Regulation (EU) No 1151/2012 does afford a transition period of up to five years for prior uses of a GI.<sup>263</sup> In order to make use of this period, prior users must show that the registration of the name would jeopardise the existence of an entirely or partly identical name and that such products have been legally marketed under that name in the territory concerned for at least five years prior to the Regulation.<sup>264</sup> This transitional period may be extended by the European Commission in duly justified cases, including where the GI has been in legal use consistently and fairly for at least 25 years prior to the registration of the GI.<sup>265</sup>

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<sup>261</sup> Regulation (EU) No 1151/2012, above n 240, art 14.2; Regulation (EC) No 1308/2013, above n 243, art 102.2; Regulation (EU) No 251/2014, above n 242, art 19.2 and Regulation (EC) No 110/2008, above n 242, art 23.2.

<sup>262</sup> Regulation (EU) No 1151/2012, above n 240, art 14.2; Regulation (EC) No 1308/2013, above n 243, art 102.2 and Regulation (EU) No 251/2014, above n 242, art 19.2. Note that Regulation (EC) No 110/2008 does not refer to the coexistence of a GI and pre-existing trademark. Above n 242.

<sup>263</sup> Regulation (EU) No 1151/2012, above n 240, art 15.1.

<sup>264</sup> Art 15.1.

<sup>265</sup> Art 15.2(a).



The reason for omitting provisions relating to continuous use may relate to the historical emphasis placed on geographical origin and names within the EU. This is particularly so in relation to wines and spirits. For example, the use of the name ‘Champagne’ has been legally protected since 1891.<sup>266</sup> In addition, a substantial number of GIs for wines and spirits are registered under a specific regional name. Presumably producers of those products would use that name where their products corresponded with the specific requirements of that name. Instances of continuous use would therefore likely be minimal. Agricultural products and foodstuffs, on the other hand, are often produced under less specific regional names or a name unrelated to the specific region, prompting use of the same name in other areas for the same or similar products. A well-known example of this is the use of the term ‘Feta’ by producers in EU Member States other than Greece who were prohibited from further use of that name after registration as a GI in 2002.<sup>267</sup> It is arguable that it was for this reason that transitional provisions were included within Regulation (EU) No 1151/2012, which applies to those products.

New Zealand, on the other hand, provides protection for the continuous and similar use of a GI. This is subject to the proviso that a person has either used a GI in trade in a continuous manner for the ten years preceding the signing of the TRIPS Agreement or has prior to that date used a GI in trade in a continuous manner and in good faith.<sup>268</sup> The reason for affording protection for continuous use under the Geographical Indications (Wine and Spirits) Registration Act may be explained by the fact that New Zealand is considered a New World country, where many of its inhabitants find their ancestral roots in older parts of the world, including Europe. As a result of immigration, traditional practices and ways of life were imported into New Zealand, including the use of traditional names. Provisions for continuous use protect those names in respect of products made in accordance with traditional practices. Traditional uses between Old and New World countries may, therefore, explain why New Zealand protects continuous use while the EU does not.

New Zealand also provides for the continued use of a pre-existing trade mark under s 30(1) of the Geographical Indications (Wine and Spirits) Registration Act. Similar to the legal

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<sup>266</sup> See Treaty of Madrid (1891), above n 13. Note that art 1(2) permits a country to secure protection for their marks by filing said marks at the International Bureau of Intellectual Property.

<sup>267</sup> Note that Germany and Denmark opposed the initial registration of ‘Feta’ as a PDO in 1999 and subsequently sought annulment of that registration on grounds of invalidity in 2002. See Joined Cases C-465/02 and C-466/02 *Federal Republic of Germany (C-465/02) and Kingdom of Denmark (C-466/02) v Commission of the European Communities* [2005] ECR I-9115.

<sup>268</sup> Geographical Indications (Wine and Spirits) Registration Act 2006, s 29(1).

approach taken by the EU, use of a pre-existing trade mark may be continued where the trade mark has been applied for, registered or established by use in good faith before the date of protection of the GI in its country of origin.<sup>269</sup>

It is important to note that although the EU does not contain provisions protecting the continuous use of a GI in its domestic law, it has included such provisions within CETA, albeit to a limited extent. Rather than exempting protection for all instances of continuous or similar use, art 20.21.2 – 4 identifies those products where continued commercial use shall not be prevented. This is provided such use has occurred for a specified duration of time prior to the date on which the CETA negotiations were concluded. Transitional periods are also provided, during which time continued use shall not be prevented for those who have used that GI in a continuous manner for less than the specified duration of time. The inclusion of these provisions in the absence of corresponding domestic laws indicates that the EU could be willing to introduce similar provisions into future trade agreements. This could temper any obligation for New Zealand to implement TRIPS-plus protection for GIs under an EU-NZ FTA.

(ii) Customary/generic terms

Registration of a generic term is prohibited within each piece of relevant EU legislation.<sup>270</sup> A term is defined as generic where the name, although it relates to the place or region where a product was originally produced or marketed, has become the common name of that product in the EU.<sup>271</sup> In establishing whether a name has become generic, relevant factors shall be taken into account, including the existing situation in areas of consumption and the relevant EU or national law.<sup>272</sup>

Use of a generic term is expressly permitted under art 41.1 of Regulation (EU) No 1151/2012. This includes where the generic term is part of a name that is protected under a GI.<sup>273</sup> Article 13.1 of that Regulation does make clear, however, that where a generic term is part of a protected GI, use of that term remains subject to conditions protecting the GI against misleading indications and where use of that term is liable to mislead consumers. While the

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<sup>269</sup> Or before the entry into force of the TRIPS Agreement, whichever is later.

<sup>270</sup> Regulation (EU) No 1151/2012, above n 240, art 6.1; Regulation (EC) No 1308/2013, above n 243, art 101.1; Regulation (EU) No 251/2014, above n 242, art 18.1 and Regulation (EC) No 110/2008, above n 242, art 15.3.

<sup>271</sup> Regulation (EU) No 1151/2012, above n 240, art 3.6; Regulation (EC) No 1308/2013, above n 243, art 101.1; Regulation (EU) No 251/2014, above n 242, art 18.1 and Regulation (EC) No 110/2008, above n 242, art 15.3.

<sup>272</sup> Regulation (EU) No 1151/2012, above n 240, art 41.2; Regulation (EC) No 1308/2013, above n 243, art 101.1 and Regulation (EU) No 251/2014, above n 242, art 18.1. Note that Regulation (EC) No 110/2008 does not contain a similar provision. Above n 242.

<sup>273</sup> Regulation (EU) No 1151/2012, above n 240, art 41.1.

use of a generic term is not expressly provided for in the remaining pieces of relevant EU legislation, use may be presumed on the basis that registration of a generic term is expressly prohibited. As registration of a name ensures protection, a term cannot be protected against use when it may not be registered. Use of a generic term may therefore be implied.

Similarly, s 12 of the Geographical Indications (Wine and Spirits) Registration Act prohibits the Registrar from registering a GI for a wine or spirit if it is identical to the term customary in common language as the common name of a wine or spirit in New Zealand. While there is no reference to generic names or the use thereof within that Act, it may also be presumed that if such a name cannot be registered, it also cannot be protected against use. Use of a generic term may also therefore be implied. On this basis, there is no effective difference between the provisions relating to customary use in the EU and New Zealand relating to generic terms.

Of note is that, under s 45(1) of the Geographical Indications (Wine and Spirits) Registration Act, “[t]he Registrar may *remove* a registered geographical indication from the register if satisfied that”, among other grounds, the GI “has become a term customary in the common language as the common name for a wine or spirit in New Zealand.”<sup>274</sup> Any proposed removal of a GI from the register may be opposed by any interested person;<sup>275</sup> however, the decision to remove a GI is ultimately one for the Registrar to make. This is in direct contrast to the approach taken under the relevant EU legislation, which all prohibit a registered GI from becoming generic.<sup>276</sup> In practice, however, the effect of s 45(1) may arguably be insubstantial as registration prohibits use of that name. As use of the name is no longer permitted other than by those whose product is legitimately covered by that GI, there is little opportunity for that particular name to fall into generic use.

Where this provision shall take most effect is where the use of a name protected by a GI is already permitted due to its continued use. This would be due to continual exposure of the generic products to consumers, which may mislead them as to the true origin of that name and its relation to a given product. One way to get around this would be to ensure that any name, the use of which is permitted by continuous use, shall be accompanied by expressions or that

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<sup>274</sup> Geographical Indications (Wine and Spirits) Registration Act 2006, s 45(1)(e) (emphasis added).

<sup>275</sup> S 45B.

<sup>276</sup> Regulation (EU) No 1151/2012, above n 240, art 13.2; Regulation (EC) No 1308/2013, above n 243, art 103.3; Regulation (EU) No 251/2014, above n 242, art 20.3 and Regulation (EC) No 110/2008, above n 242, art 15.3.

the label visibly indicates place of origin. This would contribute to distinguishing a generic product from one protected by a GI and may prevent consumers from being misled.

Finally, New Zealand prohibits the registration of a GI which is identical to a customary name of a grape variety existing in New Zealand upon entry into force of the TRIPS Agreement. This is consistent with obligations under that Agreement, which leaves the matter to each WTO Member to determine themselves.<sup>277</sup> EU legislation, in comparison, is silent on this matter. The effect of this provision is likely to be insignificant, however, as there are alternative means to protect those terms. An example is the Italian wine Prosecco, which arguably may not be capable of registration as a GI in New Zealand due to the commonality of its name.<sup>278</sup> Irrespective of this, and whether or not protection is granted by way of a GI, Prosecco already receives protection as a brand name under registered and protected trade marks.<sup>279</sup>

## 2 *‘Other’ methods of legal protection for geographical indications in New Zealand*

In the absence of a specific registration scheme other than for wines and spirits, New Zealand affords protection to GIs through other legal mechanisms. Protection may be granted through the general application of rules that may operate to prevent the misleading of consumers in respect of a product’s true geographical origin. These legal mechanisms are trade mark law, the Fair Trading Act 1986 and the tort of passing off. The following section shall discuss the applicability of those existing rules to GIs.

### (a) Trade mark law

A GI may be protected under a New Zealand trade mark provided it meets the criteria under the Trade Marks Act 2002. A trade mark may be granted for any sign that is capable of being represented graphically and which distinguishes the goods of one person from those of another, including both certification and collective marks.<sup>280</sup> In respect of a certification mark, the mark may distinguish “goods certified by any person in respect of origin, material, mode of manufacture, quality, accuracy, or other characteristics from goods not so certified”; whereas a collective mark distinguishes goods of a collective association from those of a person who is

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<sup>277</sup> TRIPS Agreement, above n 3, art 24.6.

<sup>278</sup> Note that the Consorzio di Tutela Della Denominazione di Origine Controllata Prosecco filed an application for the registration of Prosecco as a GI in New Zealand on 06 November 2017, which is currently under examination. Intellectual Property Office of New Zealand, Geographical Indications Register, IP number 1025.

<sup>279</sup> Intellectual Property Office of New Zealand, Trade Mark Register, IP Numbers 975131 and 982408.

<sup>280</sup> Trade Marks Act 2002, s 5(1) ‘trade mark’.

not a member of that collective association.<sup>281</sup> The rights afforded under a registered trade mark extend to both certification and collective marks, granting the mark holder the exclusive right to use or authorise others to use that mark.<sup>282</sup> Under a collective mark, this exclusive right extends to all members of the relevant collective association.<sup>283</sup>

GIs may be registered under any of the above-mentioned marks, one difference between them being the persons or products that a mark holder may exclude from using that particular mark. A search of the IPONZ trade mark register reveals the registration or application of a number of well-known European GIs for each type of mark. For example, the Consorzio Vini Asolo Montello has sought a collective mark that applies to Prosecco, while a collective mark has been registered in respect of Prosciutto di San Daniele. Similarly, certification marks have been granted to registered products such as Stilton cheese, Parmigiano Reggiano and Parma ham, while trade marks have been granted to registered products such as Champagne, Cognac and Riccadonna.

Although trade marks in general afford adequate protection in place of a GI, protection is weaker and limited in scope when compared with GI protection. Primarily, trade marks are registered by individual producers, which leads to the implication that there is no common standard set down for a given product. This includes standards relating to the geographical origin of that product. The purpose of the trade mark is not to protect the product and its perceived quality but rather to protect or draw attention to the brand affixed to that product. Trade marks are therefore not so much indicators of quality as they are indicators of producers. This is in contrast to a GI, the purpose of which is to protect against the dilution in value of a product where the geographical origin and quality are inherently linked.

While certification marks afford stronger protection than a sole trade mark, the standards are set down by private certifiers and may or may not require a link between geographical origin and quality. Collective marks confer the strongest protection afforded by a mark as standards designed to control product quality and integrity are set by a public consortium or organisation made up of producers of those specific products. Irrespective of this, such products may still be forced to compete against products using accompanying terms such as ‘type’, ‘style’, ‘kind’, ‘imitation’ or the like, as collective marks do not protect against such use of the mark.

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<sup>281</sup> S 5(1) ‘certification trade mark’ and ‘collective trade mark’.

<sup>282</sup> S 10(1)(a) and (b).

<sup>283</sup> S 10(2)(a).

In addition, the individualistic nature of the trade mark system places overly formalistic and tedious processes on right holders in comparison to a registration scheme when seeking protection in a foreign country. While a trade mark applicant would need to seek protection in each foreign country it wishes to have protection in, a product registered under a GI in its place of origin would automatically benefit from protection where that term is recognised as a GI by a foreign country. Finally, in the event of a dispute, infringement of a GI is easier to resolve than infringement of a mark. This is given the broader level of protection afforded to prevent the use of GIs as opposed to trade marks.

(b) Fair Trading Act 1986

The Fair Trading Act seeks to contribute to a trading environment where businesses have the ability to compete effectively and where consumers may participate confidently in knowing that their interests are protected.<sup>284</sup> To this end, the Fair Trading Act “promotes fair conduct and practices in relation to trade” by prohibiting certain forms of unfair conduct and practices.<sup>285</sup> The most frequently cited prohibition relates to misleading conduct, prohibited under s 9 which states “[n]o person shall, in trade, engage in conduct that is misleading or deceptive or is likely to mislead or deceive”. While the Fair Trading Act does not provide an interpretation for either mislead or deceit, they have been described as similarly meaning “to lead into error”, where ‘deceit’ carries a sense of “craft or overreaching”.<sup>286</sup> In addition to s 9, which may be described as a general catch-all phrase, s 13(1) prohibits false or misleading representations, including representations which relate to the quality or place of origin of a good.<sup>287</sup>

The prohibition on misleading conduct imposes a reasonably low threshold as it merely requires that conduct is capable of misleading or is likely to mislead; it does not require evidence of actual misleading. Provided that the conduct in trade is capable of or is likely to cause consumers to adopt the wrong idea or impression, the requirements of s 9 will likely be met. As an example, the use of a name protected as a GI in its country of origin, in relation to a product that is produced elsewhere, may constitute misleading conduct if the use of that name causes a consumer to adopt the wrong impression as to the true origin of the product. However, if a product clearly distinguishes itself from the GI despite adopting the same name, it is less

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<sup>284</sup> Fair Trading Act 1986, s 1A(1).

<sup>285</sup> S 1A(2)(a) and (b).

<sup>286</sup> Ian Gault and others *Gault on Commercial Law* (online looseleaf ed, Thomson Reuters) at [FT9.04].

<sup>287</sup> Fair Trading Act 1986, s 13(1)(a) and (j).

likely that the conduct would be considered misleading or deceptive. Of note is that the approach taken is reflective of consumer protection, therefore there is no obligation to provide evidence of damage to a product's goodwill or reputation.<sup>288</sup>

A misleading or false representation, on the other hand, involves the description or portrayal of something in a particular false or misleading way.<sup>289</sup> This includes "oral and written statements associated with pictorial material".<sup>290</sup> In respect of a GI, this could include the display of images or the use of a logo or sign used to illegitimately identify the product as that to which the logo or sign applies. Use of the particular images, logo or sign may falsely represent either the quality or the origin of the GI concerned. The focus here is on the display or portrayal of something in a misleading way, as opposed to the nature of the conduct itself. Of note is that s 16 of the Fair Trading Act prohibits the forging of a trademark or the application of a sign so similar to a trademark that it is likely to mislead or deceive. If a logo or sign is displayed on a product where that logo or sign is protected by a trademark, a claim could be raised under either section.

(c) Passing off

While the FTA largely focuses on consumer protection, the action of passing off was developed under the common law in order to protect business goodwill against unfair competition between traders.<sup>291</sup> It is particularly concerned with misrepresentations that have as their aim the passing off of goods as those of another, thereby appropriating the goodwill or reputation of the other.<sup>292</sup> In order to establish a claim, the party must satisfy the following three-pronged test:<sup>293</sup>

- a) there is goodwill or reputation attached to the goods or services, associated with an identifying feature;
- b) there has been a misrepresentation by the defendant, leading or likely to lead the public to believe that the goods are those of the plaintiff; and
- c) the plaintiff has suffered or is likely to suffer damage as a result of the misrepresentation.

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<sup>288</sup> Philip B Gurney, "Protecting goodwill in New Zealand wine labels – how will "geographical indications" bolster existing IP rights (if at all)?" (2008) 5 NZIPJ 484 at 488.

<sup>289</sup> English Oxford Living Dictionaries, above n 113, 'representation'.

<sup>290</sup> Ian Gault and others *Gault on Commercial Law* (online looseleaf ed, Thomson Reuters) at [FT13.09].

<sup>291</sup> Campbell Clark *Laws of New Zealand Intellectual Property: Fair Trading: The tort of passing off* (online ed) at [4].

<sup>292</sup> At [4].

<sup>293</sup> *Reckitt & Colman Products Ltd v Borden Inc* [1990] 1 WLR 491(HL) at 499.

The three-pronged test for passing off was applied in New Zealand in the case *Anheuser-Busch Inc v Budweiser Budvar National Corporation*,<sup>294</sup> which involved a dispute between the parties over the labelling of their respective beers. The plaintiff held the New Zealand trade marks for ‘Budweiser’ and ‘Bud’ beer, the names having been derived from the German name of the Czech town České Budějovice. The defendant later registered a trade mark for its rival beer ‘Budějovický Budvar’, where it included on the label the terms ‘Budweiser Budvar’. In assessing the claim of the plaintiff, the Court of Appeal rejected a claim for passing off on the basis that there was nothing in the presentation of the goods to increase the likelihood of deceit as the products were visually different.<sup>295</sup> In addition, the labels of the defendant sufficiently disclosed that the beer was a Czech lager, therefore any possible connection could not arise above “cause to wonder”.<sup>296</sup> Evidence presented in order to indicate the reputation attached to the name ‘Budweiser’ was dismissed by the Court, although that evidence was unnecessary for the Court to reject the claim. Budweiser Budvar National Corporation has since obtained a PGI for ‘Budějovické pivo upon accession of the Czech Republic to the EU.’<sup>297</sup>

Similarly, passing off has been used in New Zealand to protect the goodwill or reputation of ‘Champagne’ against winemakers seeking to appropriate that name for their own sparkling wine. In upholding a claim by French winemakers for passing off, the Court of Appeal in *Wineworths Group Ltd v Comité Interprofessionnel du Vin de Champagne* held that the requisite distinctiveness and goodwill of that name was well established in the New Zealand market.<sup>298</sup> In so holding, Justice Gault stated that “[i]t is not the name that indicates the characteristics but the name in conjunction with experience or repute. ... For suppliers the attracting force in the name constitutes a part of the goodwill of their business.”<sup>299</sup> The inevitable consequence of use of that name would be the erosion of its distinctiveness, which would undoubtedly cause damage to the goodwill and reputation of those legitimately producing Champagne.<sup>300</sup> Despite the continuous adverse use of the term Champagne, the Court held that such use had not been sufficient to dilute the distinctiveness of that term to the point that it may now be considered generic.<sup>301</sup> For these reasons, the claim for passing off was made out.

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<sup>294</sup> *Anheuser-Busch Inc v Budweiser Budvar National Corporation* [2003] 1 NZLR 472.

<sup>295</sup> At [128] – [129].

<sup>296</sup> At [130].

<sup>297</sup> European Commission: Agriculture and Rural Development “Database of Origin and Registration” (DOOR).

<sup>298</sup> *Wineworths Group Ltd v Comité Interprofessionnel du Vin de Champagne* [1992] 2 NZLR 327 at 336.

<sup>299</sup> At 336.

<sup>300</sup> At 343.

<sup>301</sup> At 340.



While French winemakers were successful in this case, it is questionable whether a less prominent or well-known name would achieve the same result. Here, the case hinged on the well-established reputation of that particular name. The problem facing other producers seeking to protect their GIs under the tort of passing off would be in evidencing the requisite goodwill and distinctiveness of their GI as compared with a product that has appropriated that term. This is particularly so in relation to agricultural products which have been produced and marketed under those names in New Zealand for an extended period of time.

*D Summary of Chapter: Determination of Challenges and Difficulties Going Forth in the Negotiations for an EU-NZ FTA*

Based on the preceding sections of this chapter, it is clear that there are significant differences in the TRIPS-plus protections relating to GIs between CETA and the CPTPP. The purpose of this section is to determine any challenges or difficulties arising from those differences that would need to be overcome during the course of negotiations.

*1 Legal protection afforded to geographical indications*

The approaches taken to the protection of GIs differ significantly between CETA and the CPTPP. Whereas the CPTPP prioritises trade marks and emphasises the role of trade marks in protecting GIs as signs, CETA affords legal protection to GIs as a distinct IPR. This is consistent with the international obligations imposed on WTO Members under the TRIPS Agreement, albeit the level of protection afforded under CETA is of a higher standard and covers a broader range of product classes. To this end it requires the protection of a number of specific names or terms pertaining to agricultural products and foodstuffs, registered in their country of origin as GIs. In addition to protecting the use of that specific name, CETA requires that protection be extended to the use of that term in conjunction with accompanying expressions such as ‘type’, ‘style’, ‘kind’, ‘imitation’ or the like. The aim is to prevent the dilution of a specific GI and its reputation by eliminating all association of generic products with that protected term.

Legal protection of GIs under CETA is broadly reflective of EU domestic law. As discussed above, the EU provides for quality schemes where producers of foodstuffs and agricultural products, wines and spirits may register a term under one of three schemes in order to obtain protection for direct or indirect use of that term. This applies against misleading use as much as deceptive use or misuse, and similarly extends to accompanying expressions and

translations. An earlier agreement between the EU and Canada was incorporated within CETA to address the protection of wines and spirits. Given the consistency between EU domestic law and CETA in relation to the protection of GIs, it may be inferred that CETA is broadly reflective of EU interests and priorities as opposed to the interests and priorities of Canada. This proposition is supported by the fact that all GIs specifically included in CETA as names to be protected belong to EU Member States; none listed therein belong to Canada.

New Zealand has only recently implemented a register for wines and spirits in compliance with its obligations under the TRIPS Agreement. This permits GI holders to seek registration of a name in order to ensure its protection against use. Whereas EU law protects against direct or indirect use, which includes presentation and labelling, New Zealand protects against actual use of the GI, providing a stricter standard. The main difference lies in the product classes that are protected under each Party's registration scheme, with the New Zealand scheme only applying to wines and spirits and not foodstuffs or agricultural products. Despite this, New Zealand offers other legal mechanisms that apply generally to protect GIs: trade mark law, the Fair Trading Act and the tort of passing off. These mechanisms offer various methods of protecting a GI by way of mark or sign registration, misleading or deceptive conduct or misleading representation as to quality or origin, and the erosion of distinctiveness thereby damaging goodwill and reputation. That said, each mechanism presents its own hurdles or process burdens while a registration system provides a streamlined process to the ease of GI holders. It also upholds GIs as a class of IP in its own right. For these reasons, it is very likely that the difference in protection schemes between the Parties will present challenges or difficulties that the Parties would need to overcome in the course of negotiations.

The CPTPP broadly reflects the domestic law of the Parties to that agreement, which includes, to a large extent, those of New Zealand. Because of this, the provisions relating to GIs within that agreement predominantly apply to ensure the implementation of certain procedures where GIs are protected other than by trademark. Such procedures include opposition and invalidation procedures, which has implications in respect of trade agreements which seek to accord protection to distinctive signs under a GI. This shall be discussed further below. Otherwise, the CPTPP places priority on trade mark protection which arguably seeks to rollback protection afforded under a GI. That said, both CETA and the CPTPP protect pre-existing rights, therefore a subsequent trade mark will not invalidate an existing GI and vice versa.

## 2 *Exceptions to legal protection afforded to geographical indications*

### (a) Grandfathering/continuous use

EU domestic legislation does not permit continuous use of a GI other than where there is a pre-existing trademark. A transitional period of up to five years is, however, permitted where there has been prior use of a GI relating to agricultural products and foodstuff only. The reason for this may lie in the particular product classes to which GI protection is afforded and the specificity of GI names to a particular region, which renders illegitimate marketing of a GI less likely. New Zealand, on the other hand, does provide protection for continuous use. As discussed above, the reason for this is in recognition that traditional practices and ways of life have been imported to New Zealand through immigration. Continuous use provisions, therefore, permit traditional users to continue producing products in accordance with those traditional ways.

It is important to note that despite the EU's domestic position, CETA affords protection, albeit limited in scope, to contentious GI names where there has been continuous use. This may indicate the willingness of the EU to negotiate limited exceptions in order to secure protection for GIs in its trade agreements with third parties.

Both Canada and New Zealand are relatively similar with respect to immigration and the importation of traditional practices and ways of life, both being examples of New World countries. Whether New Zealand should afford protection to GIs other than wines and spirits in an EU-NZ FTA is a matter that the Parties will need to determine during the course of their negotiations. This will involve a consideration of those GI terms currently protected by another producer under a New Zealand trademark and whether continuous use of those names will be permitted under an EU-NZ FTA.

### (b) Customary/generic terms

EU law permits use of a generic term, either by express or implied permission, as discussed above. In respect of use by express permission, this applies even where the generic term is part of a name that is protected under a GI. It does, however, make clear that use of that generic term remains subject to conditions protecting the GI against misleading indications or misleading of consumers. In respect of use by implied permission, EU law prohibits the registration of a generic term. It may be presumed that, if a term cannot be registered, it also cannot be protected against use, hence permission to use is implied. Similarly, New Zealand

impliedly permits the use of a generic term by prohibiting the registration of a term identical to the term customary in common language. On this basis, there is no effective difference between the domestic approaches of the Parties in order for any challenge or difficulty to arise in respect of customary or generic terms.

New Zealand does permit the removal from the register of a GI where the registrar is satisfied that the name has become customary in the common language. Where this may cause issues is in relation to continuous use of a GI, where the continual exposure to a generic product may over time mislead consumers as to true origin and ultimately bring that name into the common language. This may, therefore, be an issue which the parties may wish to discuss further in the course of negotiations, should the parties agree to permit continuous use for certain GI names.

## V *Implications for New Zealand*

The purpose of this chapter is to discuss the implications arising from the challenges posed by protections relating to patent term extension/restoration, data and market exclusivity, and the protection of GIs, in light of the Parties' respective positions and interests. In so doing, the issue of whether New Zealand *should* implement TRIPS-plus protections and to what extent shall be discussed, along with how existing international obligations may be reconciled.

### A *Towards an EU-NZ Free Trade Agreement*

The respective positions of the Parties towards the protection of IP are naturally reflective of their IP manufacturing capabilities. As already mentioned above, the EU is a high producer of IP while New Zealand is a high consumer of IP, therefore it is no surprise that the EU provides a stronger level of domestic protection than New Zealand. This is not to say that New Zealand does not provide *adequate* IP protection. Rather, the levels of protection afforded in each party reflect an appropriate balance between the competing interests of right holders and consumers in that respective party. Each party may, therefore, be said to effectively and efficiently protect IPRs domestically to a level that meets their respective needs.<sup>302</sup>

The present issue is that the EU seeks to export its norms in its international agreements in order for EU producers to achieve the same or similar level of protection for their goods in a foreign market, thereby levelling the playing field. This is the case in CETA, which is broadly reflective of EU law. The exportation of norms may be to the disadvantage of the trading partner as the level sought has the effect of skewing the balance between the interests of right holders and those of consumers in that country, often to the detriment of consumers. In the case of New Zealand, given its domestic position, the imposition of those TRIPS-plus protections identified as posing a significant challenge will very likely have this effect. The challenge going forward in the negotiations is, therefore, in upholding and attaining the interests of both Parties in a manner that avoids or minimises harm.

Both the EU and New Zealand have made it clear that an IP chapter should include mutually beneficial provisions on the protection and enforcement of IPRs.<sup>303</sup> It has also been made clear

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<sup>302</sup> Ministry of Foreign Affairs and Trade "EU-NZ Free Trade Agreement: New Zealand and EU approaches to intellectual property in trade agreements" <<https://www.mfat.govt.nz/assets/FTAs-in-negotiations/EU-FTA/Information-package/New-Zealand-and-EU-approaches-to-intellectual-property-in-trade-agreements.pdf>> at 1.

<sup>303</sup> At 1.

that, where New Zealand does make commitments in sensitive areas of IP, the focus will be on ensuring the minimisation or avoidance of any costs or disadvantages.<sup>304</sup> These elements comprise the starting approach to any discussions on how TRIPS-plus protections may be included within an EU-NZ FTA.

*B Implementation of TRIPS-plus protections: a balance of interests and possible outcomes*

In order to enhance global competitiveness, the EU contends that stronger IP protection is necessary outside of the domestic sphere. To this end, the vulnerability of creativity, research and design in other jurisdictions was acknowledged by the European Commission in its trade policy *Trade for All*, compelling the EU to step up the protection and enforcement of IPRs in its FTAs.<sup>305</sup> The aim is to promote international harmonisation through the broad alignment of rules, creating a more predictable and certain IP environment.<sup>306</sup> As the overall objective is to promote a stronger level of protection for IPRs, the EU takes as the starting point in its FTAs similar levels of protection as its domestic law, thereby promoting harmonisation at the level it deems sufficient to adequately protect the interests of EU right holders. On this basis, it may be expected that a similar approach be taken towards the protection of IPRs in an EU-NZ FTA.

Despite taking as a starting point levels of protection similar to its domestic law, the EU does “calibrate [their] level of ambition to the partner country’s level of development”.<sup>307</sup> In a strict sense ‘development’ may be interpreted as meaning the economic development of a country relative to other nations. This interpretation would be consistent with the European Commission’s Communication on a strategy for the protection and enforcement of IPRs in third countries, which does state that a limited set of IPR provisions “may be considered” for least-developed countries and poorer developing countries.<sup>308</sup> However, this interpretation disregards the practical realities that some countries, like New Zealand, are developed yet are also small market economies. The implication is that their interests can align with those of either other developed or developing countries.<sup>309</sup> In this case, it may be arguable that a limited

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<sup>304</sup> At 2.

<sup>305</sup> European Commission “Trade for all: Towards a more responsible trade and investment policy” (2015) at 2.1.7.

<sup>306</sup> European Commission *Communication from the Commission to the European Parliament, the Council and the European Economic and Social Committee: Trade, growth and intellectual property – Strategy for the protection and enforcement of intellectual property rights in third countries* (01 July 2014) COM 389 final at 14.

<sup>307</sup> At 15.

<sup>308</sup> At 15.

<sup>309</sup> Frankel, above n 90.

set of IPR provisions should be considered as a starting point in recognition of this unique position. That said, an international agreement is ultimately a multi-party creation. While the starting point may propose stronger protection than what one party is willing to commit to, there must be some give and take in order to recognise and give effect to the other party's interests or reservations. If not, then an agreement will not be reached.

### *1 Protection for pharmaceuticals*

The protection of IPRs is paramount to the EU pharmaceutical sector, which relies heavily on those rights in order to protect and promote innovation. Conditions that stimulate creativity and innovation are therefore required in order for pharmaceutical companies to invest in research and development, so that they may deliver life-saving pharmaceutical products to those in need. Without such conditions, investors would shy away from investing in innovative solutions to medical challenges. A strong and robust IP framework which incentivises research and development through stronger protection is therefore crucial to securing investment and consequently enhancing the competitiveness of the EU pharmaceutical sector in an increasingly global world.<sup>310</sup> It is for this reason that the EU promotes the inclusion of TRIPS-plus protections for pharmaceuticals within its trade agreements, particularly protections relating to patent term extension/restoration and data and market exclusivity.

With that being said, it is questionable whether stronger protection for pharmaceuticals may be justified based upon the economic underpinnings for granting rights in IP.

The basic premise behind pharmaceutical protection by way of IPRs is that innovators must be allowed to reap what they sow. While the creation of an idea is potentially unlimited, there will usually be a cost in the production or development of that idea. As a result, an innovator will seek to recoup their costs, ordinarily by imposing a price to access the idea or its product. If an innovator cannot obtain an appropriate return for the development of that idea, there will be little or no incentive to invest in innovation.<sup>311</sup> This also leads to a social cost as the inability to recoup sunken costs by excluding access to an idea or its product deters an innovator from creating and developing ideas. This includes ideas which, once developed, produce social benefits such as the production of life-saving medicines. Thus, by establishing property rights

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<sup>310</sup> European Federation of Pharmaceutical Industries and Associations *Future-proofing EU competitiveness by limiting the negative impact of the SPC manufacturing waiver* (January 2019) at 4.

<sup>311</sup> Stanley M Besen and Leo J Raskind "An Introduction to the Law and Economics of Intellectual Property" (1991) 5(1) JEP 3 at 5.

in IP an innovator has an incentive to invest in innovation, as it allows them to recoup their costs by excluding access to ‘free-riders’ who would otherwise copy or freely use their ideas.

On the other hand, excluding others from accessing ideas limits the diffusion of those ideas and prevents people from benefitting from what would otherwise be a public good. In economic terms, IPRs prevent competition by providing the right holder with a monopoly over their idea.<sup>312</sup> This runs against free market principles as competition ensures the efficient allocation of resources.<sup>313</sup> As lack of competition imposes a social cost, IPRs may only be justified by a public goods approach if an appropriate balance is struck which encourages the creation and dissemination of ideas while offsetting societal costs resulting from restricting competition.<sup>314</sup> The result is known as the ‘access-versus-incentive’ trade-off: reducing access to an innovation (public good) in the contemporary, thereby making it artificially scarce, increases the incentive to innovate thus generating a future social benefit.<sup>315</sup>

Care must, however, be had in ensuring an appropriate balance is struck between the interests of right holders in protecting their IP and the interests of consumers in using that IP. Excessive protection may lead to what economists’ call ‘rent-seeking’, defined as “a return over and above the cost of generating the return”.<sup>316</sup> In other words, it is pure profit. This may lead to over-innovation in activities that produce larger returns and under-innovation in those that do not.<sup>317</sup> This is irrespective of the social benefits arising from the latter. Furthermore, excessive protection does not necessarily mean that new innovations arising as a result of that protection will be socially beneficial.<sup>318</sup> This is because increased creative activity does not necessarily lead to the use of new innovations.<sup>319</sup> For these reasons, policy makers must ensure that the

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<sup>312</sup> Robert P Merges, Peter S Menell and Mark A Lemley *Intellectual Property in the New Technological Age* (3<sup>rd</sup> ed, Aspen Publishers, New York, 2003) at 13.

<sup>313</sup> At 13.

<sup>314</sup> At 13.

<sup>315</sup> William M Landes and Richard A Posner *The Economic Structure of Intellectual Property Law* (Harvard University Press, Cambridge MA, 2003) at 20-21

<sup>316</sup> At 17.

<sup>317</sup> Note that the World Health Organisation has comprehensively reported on the underproduction of pharmaceutical products which treat diseases common to third-world countries, such as Ebola, Malaria and Tuberculosis, noting that incentive structures encourage pharmaceutical companies to instead target their products towards affluent Western societies who have sufficient purchasing power. See Commission on Intellectual Property Rights, Innovation and Public Health *Public Health, Innovation and Intellectual Property Rights* (World Health Organisation, Report, 03 April 2006), at 15-17.

<sup>318</sup> Besen and Raskind, above n 311, at 6.

<sup>319</sup> At 6.



level of IP protection is sufficient in order for right holders to reap no more than what they sow.

From an economic perspective, the issue with imposing TRIPS-plus protections for pharmaceuticals is that it changes the balance struck between the interests of right holders in protecting their IP and the interests of consumers in using that IP. This may be appropriate in IP producing states, the cost of innovation has increased since the TRIPS Agreement was concluded, in order to ensure that pharmaceutical manufacturers do indeed reap what they sow. However, it may not be appropriate in IP consuming states where restricting access to pharmaceuticals would impose a much greater social cost. What may be economically sound for one state is not necessarily economically sound for another. Care must therefore be taken by policy makers when determining whether to implement TRIPS-plus protections in order to ensure an appropriate balance is maintained and is consistent with their economic position.

(a) Patent term: extension/restoration

The EU has submitted for discussion to New Zealand a draft IP chapter for inclusion within an EU-NZ FTA which includes a provision for patent term extension. The operative clause within that provision requires each party to provide a period of further protection for a pharmaceutical product which is protected by a patent for a period of time equal to that which elapses between the patent application date and the date of marketing authorisation.<sup>320</sup> This is to be reduced by a period of [...] years, while the duration of that protection may not exceed [...] years.<sup>321</sup> Substituting [...] for [five] years and [a period of two to five years] respectively, the proposed provision is identical to art 20.27.5 – 6 of CETA – of which there is a high degree of similarity to EU domestic law. Considering the interest of the EU in promoting stronger levels of IP protection in its FTAs and the relationship between the above proposed provision and CETA, it may be assumed that the EU is seeking to enforce within an EU-NZ FTA a level of protection similar to its domestic law, even though the proposal purposively omits any specific periods of time that would otherwise be referred to within that provision.

While the determination of length of time has been left to the parties to discuss during the course of negotiations, any determination must be seen as arbitrary. As identified above, New Zealand does not permit patent term extension. Nor is it obliged to implement such a scheme

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<sup>320</sup> European Union “Proposal for the EU-New Zealand FTA: Chapter [XX], Intellectual Property” (13 June 2018) art X.41.2, available at <[http://trade.ec.europa.eu/doclib/docs/2018/july/tradoc\\_157204.pdf](http://trade.ec.europa.eu/doclib/docs/2018/july/tradoc_157204.pdf)>.

<sup>321</sup> Arts X.41.2 and X.41.3. Where [...] is to be determined by the parties in the course of negotiations.

as the CPTPP suspended the provisions pertaining to patent term extension. The determination of a particular number would therefore be seen as a random choice following no obvious reason or system on the part of New Zealand other than in order to form a compromise. Not only is the determination of a specific period of time arbitrary but it may be seen from one perspective as irrelevant; for the effect of the provision is to oblige New Zealand to provide for a period of patent term extension, regardless of any reference to length of time. By requiring New Zealand to provide for a period of patent term extension, the EU has sought to enforce within an EU-NZ FTA a similar level of patent protection to its domestic law that is above the level already provided by New Zealand.

Consequently, the issue that New Zealand would face in relation to patent term extension is whether or not it should implement such a provision and, if so, to what extent.

Any implementation of a patent term extension scheme would have the consequence of delaying the entry of generic pharmaceutical products onto the New Zealand market. As a high net user of IP, New Zealand has a strong interest in enabling rapid entry onto the market of generic products upon expiry of a patent in order to ensure that consumers have prompt access to affordable medicines. Until generic entry occurs, the patented product may often be unaffordable due to the monopoly enjoyed by the originator manufacturer. This is compounded by the purchasing approach taken by New Zealand's Pharmaceutical Management Agency, where generic products are purchased over patented products in order for more products to be subsidised. The unavoidable consequence of implementing a patent term extension scheme is that a life-saving pharmaceutical product may be protected for a further period of time after expiry of the patent term, to the severe detriment of those who rely on that product to live.

Issues surrounding affordability have recently been highlighted by the European Parliament, which in a 2016 report noted that over the past decades the price of new medicines had increased to the point of being unaffordable to many EU citizens, thereby threatening the sustainability of national health care systems.<sup>322</sup> The report continued to deplore the increase in litigation cases aiming to delay generic entry, pointing out instead that biosimilar medicines enable competition thus improving access to medicines and stressing that their market entry should not be delayed.<sup>323</sup> This would seemingly provide support for refusing to implement a

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<sup>322</sup> European Parliament, "Motion for a European Parliament Resolution on EU options for improving access to medicines" (2016/2057(INI)) at I (preamble).

<sup>323</sup> At 19 and 21.

patent term extension scheme. A 2015 report also of the European Parliament highlighted the need for a “more ambitious strategy concerning the protection of intellectual property rights vis-à-vis its trading partners”.<sup>324</sup> On the one hand, it may be assumed that the 2016 report indicates a change in political thinking by placing emphasis on consumers over right holders, thereby casting the net to eliminate those TRIPS-plus protections which delay generic entry onto the market. A more plausible inference may, however, be that the delay in generic entry has more to do with unfair or unreasonable litigation than the imposition of protections of a TRIPS-plus nature that require a stronger level of protection.

Within that 2015 report, the European Parliament passed comment on the benefits that may arise from stronger protection of IPRs, by stating that it was “convinced that better protection of intellectual property rights and effective implementation of related rules in third countries would be a strong incentive for investors from the European Union and elsewhere to invest”.<sup>325</sup> Indeed, a cursory product search on the website of Medsafe reveals that many pharmaceutical products registered and sold in New Zealand under their tradenames are owned and manufactured by foreign pharmaceutical companies in Europe or other parts of the world. For example, Nurofen is manufactured by the British company Reckitt Benckiser, Keytruda by Merck Sharp & Dohme (a subsidiary of the United States company Merck & Co), Elevit by the German company Bayer and Valium by the Swiss company Roche. While the above pharmaceutical companies for the most part have registered subsidiaries sponsoring their products in New Zealand, the products themselves are manufactured elsewhere and imported to New Zealand. This means that investment in research and development is not occurring in New Zealand.

This point is picked up on by Medicines New Zealand in its submission on the implementation of the IP chapter under the TPP Agreement.<sup>326</sup> In that submission it is similarly contended that patent term extensions will encourage more innovative activity in New Zealand. This not only extends to investment in innovation but would include increased filing of patent applications by innovative pharmaceutical companies.<sup>327</sup> The reasoning behind this is that, if a company may reclaim some time lost during the patent application and market authorisation processes, thereby increasing the effective patent term, there is more incentive for that company to apply

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<sup>324</sup> European Parliament, “Motion for a European Parliament Resolution on Strategy for the protection and enforcement of intellectual property rights in third countries” (2014/2206(INI)) at B (preamble).

<sup>325</sup> At 48.

<sup>326</sup> Jarvis, above n 118.

<sup>327</sup> At (8).

to patent and sell its pharmaceutical product in New Zealand. This particularly holds true if the patent term extension applies beyond the pharmaceutical substance to cover new uses, delivery mechanisms or formulations, given the increasing research into new uses for existing active ingredients.<sup>328</sup>

It may be necessary to exercise a degree of caution when examining the benefits of implementing patent term extension within New Zealand. On the one hand, the implementation of patent term extension may indeed provide an incentive for innovative pharmaceutical companies to seek patent protection in New Zealand, thereby introducing a wider range of necessary medicines to the New Zealand market and benefiting society at large. On the other hand, those new products would nevertheless be subject to both patent protection and extended protection – as would every other pharmaceutical product under patent in New Zealand. The implication is that those products for which patent protection would have been sought in New Zealand, irrespective of the existence of any patent term extension, could now obtain extended protection, thereby extending the exclusive monopoly of the right holder for that product and ensuring a higher price (in comparison to the generic drug) is retained for a longer period of time. At a cost of \$670,000 per patient per year, the pharmaceutical product marketed in New Zealand under its tradename Soliris and used to treat the rare blood disease Paroxysmal Nocturnal Hemoglobinuria is already unaffordable to those who require that product.<sup>329</sup> Enactment of patent term extension would only serve to keep sufferers of that disease or others like it from accessing life-saving medicine. There is no benefit to society in this.

Given New Zealand's relative population size and share of the global market, there is no guarantee that an innovative pharmaceutical company would perceive the patent term extension provisions as an incentive and therefore seek patent protection in New Zealand. New Zealand's market share in pharmaceutical sales represents a tiny drop in the ocean, so it is arguably not a lucrative market for a pharmaceutical company who desires to recoup the costs of research and development.<sup>330</sup> New Zealand's small population size reinforces this as there may very likely be less people who require that specific pharmaceutical product. That said, any company who seeks patent protection in New Zealand is unlikely to be doing so primarily to recoup costs. The motivation instead could be either moral, to ensure global access to medicines, or rent-

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<sup>328</sup> At (15).

<sup>329</sup> PHARMAC "Citing unreasonable price, PHARMAC declines eculizumab funding proposal" (11 December 2013, last updated 03 March 2016) <<https://www.pharmac.govt.nz/news/media-2013-12-11-eculizumab/>>.

<sup>330</sup> Note that in 2017, North America, Europe and Japan alone accounted for 78% of all global sales. See European Federation of Pharmaceutical Industries and Associations *The Pharmaceutical Industry in Figures* (2018) at 14.

seeking. If this were the case, however, patent term extension would offer little incentive for that company to seek patent protection in New Zealand anyway.

Whether or not New Zealand should implement patent term extension, it is clear from the above that the EU's proposed provision is not mutually beneficial to both Parties, nor does it minimise or avoid the risk of harm to New Zealand and its society. The provision as it stands may likely be considered unacceptable to New Zealand.

One option for minimising the risk is to implement a TPP-style patent term extension scheme, the primary aim being to compensate right holders where there are unreasonable delays in the patent or market authorisation processes. This may be in accordance with the interests of the EU, as the introduction of the SPC was in recognition of the length of time that elapses between the filing of a patent and the granting of marketing authorisation and the subsequent insufficiency of effective patent protection. This may be interpreted to include unreasonable delays. As emphasised by the Ministry of Foreign Affairs and Trade (MFAT) in its National Interest Analysis of the TPP Agreement, it would be unlikely that the implementation of patent term extension under that Agreement would result in significant costs. The reason for this is that both IPONZ and Medsafe have efficient processing times. Consequently, very few delays would be expected to occur so an extension would rarely be granted.

The fact that extensions may only be offered in the event of unreasonable delays or curtailment may, however, be deemed unsatisfactory to the EU. As already mentioned, the SPC takes into account the length of time between the filing of a patent and the granting of marketing authorisation. This is irrespective of whether that length of time may or may not constitute an unreasonable delay. Justification for this may be found in the preamble of Regulation (EC) No 469/2009 which states that the lapse of time “makes the period of effective protection under the patent insufficient to cover the investment put into the research”, which “leads to a lack of protection which penalises pharmaceutical research”.<sup>331</sup> It is not the delay that is the issue, but the overall time it takes to get a pharmaceutical product onto the market and the consequent loss of protection resulting from the entire process.

The approach taken by the EU takes into account the entire length of time between patent filing and the grant of marketing authorisation. This is in comparison to the approach under the TPP Agreement which separates that time into two distinct periods. The first relates to delays in the

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<sup>331</sup> Regulation (EC) No 469/2009, above n 161, preamble at (4) and (5).

patent approval process while the second relates to delays in the market authorisation process. One significant implication is that the patent term adjustment scheme under the TPP Agreement only takes into account delays attributable to the relevant authorities in their examination of either patent application or application for marketing authorisation. It does not take into account the length of time necessary to conduct the relevant tests and trials in determining whether the product is viable, safe and effective before an application for marketing authorisation can be made. It has been suggested that, from a practical perspective, delays attributable to the testing phase are necessary in order to apply for marketing authorisation, so should be taken into account.<sup>332</sup> A fairer method would be to take into consideration the time taken during the testing phase, minus any time during which the applicant failed to act with due diligence.<sup>333</sup> Such an approach may result in the granting of more extensions, depending upon the consideration given to the time taken in the testing phase, but may go towards reconciling the interests of both New Zealand and the EU towards patent term extension within an EU-NZ FTA.

Alternatively, the Parties may agree to the provision proposed by the EU, provided that the method of implementing that obligation is a matter for the Parties to determine for themselves. This may provide New Zealand with some flexibility in order to tailor the obligation to its domestic situation; however, it would require New Zealand to take into account the testing phase within a patent term extension scheme. In addition, it would require New Zealand to commit to providing a maximum period of patent term extension, which it already proposed to do under the Trans-Pacific Partnership Agreement Amendment Act 2016.<sup>334</sup> Of note is that it has been suggested by Medicines New Zealand that to impose a maximum duration of extension is both arbitrary and unnecessary, as the intention behind patent term extension is compensation. Moreover, a cap on the duration of extension may not fully compensate right holders for the loss they have actually incurred, resulting in an unfair outcome.

Any provision relating to patent term extension will be a matter for the parties to determine, on the basis of whether the provision is mutually beneficial or, if not, whether the risks may be minimised. The above merely seeks to provide elements that the parties may consider during

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<sup>332</sup> Jarvis, above n 118, at (11).

<sup>333</sup> At (11).

<sup>334</sup> Trans-Pacific Partnership Agreement Amendment Act 2016, s 75 (Subpart 10A – Extension of term). Agreement not in force.

the course of negotiations and possible outcomes, where the aim is to reconcile the differing interests.

(b) Regulatory protection: data and market exclusivity

The draft IP chapter submitted by the EU for proposed inclusion within an EU-NZ FTA also provides a provision for the protection of data submitted in order to obtain an authorisation to put a pharmaceutical product on the market. In sum, art X.45 of the draft proposal requires the Parties to protect commercially confidential information against disclosure to third parties and requires that the Parties ensure both a period of data and market exclusivity. The specific requirements for each period of exclusivity are consistent with EU domestic law. Under the draft proposal, each Party shall provide an [8]-year period of data exclusivity where the marketing authority may not accept a subsequent application that refers to the results of preclinical tests or trials submitted by the originator manufacturer.<sup>335</sup> This period shall be increased in order to provide in total a [10]-year period of market exclusivity where a generic product subsequently authorised on the basis of the originator's preclinical test data may not be placed on the market without express consent of the originator.<sup>336</sup> An additional one-year period of market exclusivity shall be provided to extend the total market exclusivity period to [11]-years if the originator has subsequently obtained marketing authorisation for one or more new therapeutic indications.<sup>337</sup> This '8+2+1' structure is identical in effect to art 14.1 of Regulation (EC) No 726/2004. It may be concluded that, similarly to patent term extension, the EU is seeking to enforce within an EU-NZ FTA a level of protection similar to its domestic law.

The provision pertaining to data and market exclusivity specifically inserted the length of time for which the EU expects those exclusivity periods to apply. This may be interpreted to mean that the EU has a higher expectation for the respective periods of time than what it did in relation to patent term extension. It could also be interpreted that it was known to the EU that the imposition of an obligation pertaining to data and market exclusivity would not cause as much contestation as would a provision on patent term extension. Therefore, a higher period of time was set in recognition that, while the provision may not likely be removed, the term of exclusivity would likely be reduced in the course of negotiations. Support for this latter

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<sup>335</sup> European Union "Proposal for the EU-New Zealand FTA", above n 320, art X.45.2.

<sup>336</sup> Art X.45.3.

<sup>337</sup> Art X.45.4.

proposition may be found in an impact assessment conducted by the EU in 2017 with respect to an EU-NZ FTA, where specific issues in IPRs were identified by EU business respondents as including in the area of patent term extension, yet no reference was made to either data or market exclusivity.<sup>338</sup>

New Zealand already applies a maximum five-year period of data exclusivity in order to protect preclinical test data submitted to the marketing authorities from being used in support of any other application for marketing authorisation. It does not, however, provide for a period of market exclusivity. Consequently, the issue that New Zealand would face in relation to data and market exclusivity is whether or not it should adopt a period of market exclusivity and/or whether it should increase the current period of data exclusivity.

Any implementation of either a longer period of data exclusivity or the adoption of a period of market exclusivity would have the effect of endangering the swift entry of generic pharmaceutical products onto the New Zealand market. Due to the costs involved in conducting clinical trials, generic manufacturers rely upon the data submitted by the originator manufacturer in order to market their product, thereby keeping the cost down. A longer period of data protection has the effect of delaying the ability of a generic manufacturer to access and rely upon that data, which in turn delays the marketing of their product. In addition, a longer period of data protection could have the unintentional consequence of deterring a generic manufacturer from obtaining marketing authorisation in New Zealand. The effect would be to lessen competition, driving prices up. Any increase in data protection would, therefore, come at a significant cost to consumers as it hinders the availability of affordable medicines.

The same may be similarly said should New Zealand adopt a period of market exclusivity. Ordinarily, market exclusivity applies after the expiry of the period of data exclusivity, so that a generic manufacturer may obtain marketing authorisation through the access to and reliance on the originator manufacturer's data but may not place their product on the market until the period of market exclusivity expires. Consequently, the period of market exclusivity *extends beyond* the period of data exclusivity, further delaying the entry onto the market of generic pharmaceutical products.

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<sup>338</sup> European Commission *Impact Assessment: Accompanying the document: Recommendation for a Council Decision authorising the opening of negotiations for a Free Trade Agreement with New Zealand* (Commission Staff Working Document, 2017) COM 469 final, at 62.



That said, a manufacturer may not market their generic product until the expiry of the patent term; otherwise, they run the risk of infringement proceedings for breach of the valid patent. Although it is not impossible, in many cases it is unlikely that the data (or any market) exclusivity period will run beyond the expiry of the patent term. This is particularly so in relation to small molecule pharmaceutical products, given that they are relatively simple to develop and are cheap and easy to reproduce.<sup>339</sup> On this basis, it may be said that an extended period of data or market exclusivity would have little effect as the patent would prevent the marketing of a generic product otherwise.

The situation may be different in the case of biologics, which are complex and expensive to develop, and which take much longer to bring to market.<sup>340</sup> As a result, patent approval may take an extended period of time, which pushes back the period of data exclusivity so that both patent and data exclusivity expire at the same or a similar time. It could be that an extension to data exclusivity has the consequence that the patent expires first. While a biosimilar would ordinarily be able to come on to the market upon patent expiry, that biosimilar may not obtain the data in which to acquire market authorisation for its product if data exclusivity still applies. The implication is that the originator product effectively receives an informal extension to its patent term due to the extended monopoly granted through data exclusivity.

Given the complexity and expense required to bring a biologic to market, it would be assumed that an increased period of data exclusivity would be sought for biologics as opposed to small molecule products. On the contrary, the constraints imposed by their complexity and expense already provide strong barriers to market entry, including the market entry of biosimilars.<sup>341</sup> This is due to the expertise and financial resources required in order to develop biosimilar products. Even where a generic manufacturer does develop biosimilars, the composition of biologics is such that biosimilars would need to have their own trials conducted to a limited extent, even where reliance is on previously submitted data. This means that while introducing a generic product for a small molecule will bring about a price reduction of approximately 80–90%, introducing a biosimilar will bring about a price reduction of approximately 10–50% instead.<sup>342</sup>

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<sup>339</sup> “Biologics in Trans-Pacific Partnership Negotiations (TPP) – Full Analysis” (Obtained under Official Information Act 1982 Request to Council of Trade Unions Economist and Director of Policy, Bill Rosenberg) at 13.

<sup>340</sup> At 13.

<sup>341</sup> At 52.

<sup>342</sup> At 31.

In a report on biosimilars, the US Federal Trade Commission contended that anything beyond five-to-seven-year periods of data protection could provide excessive monopoly protection to right holders and cause unnecessary delays in the access to affordable health.<sup>343</sup> In the TPP Agreement, a period of five–eight years of data and market exclusivity was agreed upon as opposed to five years for small molecules. The imposition of a general ten-year period in comparison, as proposed by the EU, is beyond what may be considered reasonable.

In any event, given New Zealand’s reliance on generic products and the significance attached to ensuring swift entry on to the market so as to make prices affordable, it may be said that the provision relating to data protection is not mutually beneficial, nor does it minimise harm to New Zealand.

Any extension to data exclusivity, or the adoption of market exclusivity, does not minimise harm to New Zealand but rather creates it. There is no real benefit to New Zealand in implementing increased periods of data protection. A suitable alternative that would seek to minimise harm would be to lock in the existing policy by obliging New Zealand to commit to its present five-year period of data exclusivity. Currently, New Zealand may amend its laws as it sees fit in this regard. By locking in the policy New Zealand would be bound to that level, thereby limiting New Zealand’s future ability to modify those rules, even where the domestic situation requires it.<sup>344</sup> While this constitutes a new obligation for New Zealand, it is an obligation that does not directly disadvantage New Zealand. At the same time, it indicates a commitment to the EU to ensure the current levels are maintained.

It is important to reiterate that presently data exclusivity only applies to innovative medicines under s 23A of the Medicines Act, which excludes all data pertaining to second uses for a known substance. As innovation slows, pharmaceutical companies are turning more towards repurposing known products than formulating new substances. A recent study found that of pharmaceutical patents submitted for approval to the US authorities, 78% related to existing substances.<sup>345</sup> Provided that New Zealand retains the exclusion to data protection by way of innovative medicines, it may be that an extension to data exclusivity will have less impact than initially believed.

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<sup>343</sup> At 42.

<sup>344</sup> Ministry of Foreign Affairs and Trade *Trans-Pacific Partnership: National Interest Analysis* (25 January 2016) at 4.17.2.

<sup>345</sup> Robin Feldman “May your drug price be evergreen” (2018) 5(3) JLB 590 at 597.

Any provision relating to data and market exclusivity will be a matter for the parties to determine, on the basis of whether the provision is mutually beneficial or, if not, whether the risks may be minimised, or as a bargaining chip. The above merely seeks to provide elements that the parties may consider during the course of negotiations and possible outcomes, where the aim is to reconcile the differing interests.

## 2 *Protection of geographical indications*

The protection of GIs is of “core, cultural and economic importance” to the EU.<sup>346</sup> Given the traditional values underpinning regional names and the extensive quality schemes that provide for the protection of GIs as their own separate IPR within the EU, it is no surprise that the EU seeks obligations for the protection of GIs within its trade agreements. The approach taken by the EU towards an EU-NZ FTA will undoubtedly be no exception to this.

Consistent with the approaches taken under CETA and its own domestic law, the draft IP chapter submitted for discussion by the EU proposes the protection of a number of specified GIs annexed to that chapter.<sup>347</sup> The level of protection sought is identical to that stipulated within art 13 of Regulation (EU) No 1151/2012: being direct or indirect commercial use of a registered name, any misuse, imitation or evocation, even if the true origin is indicated or the name is either translated or used with accompanying expressions; other false or misleading use as to origin, nature or qualities; and any other practice liable to mislead as to the true origin.<sup>348</sup> Of those GIs annexed to the proposed IP chapter, 172 names for which protection is sought are agricultural products and foodstuffs while the remainder are wines and spirits.

New Zealand protects GIs through numerous legal mechanisms, including a registration scheme for GIs for wines and spirits. Agricultural products and foodstuffs are protected through trade mark laws and consumer protection law instead. The lack of specific protection for agricultural products and foodstuffs has been criticised by the European Commission, which in a recent impact assessment highlighted the perceived insufficiencies to the protection of GIs in New Zealand, particularly for EU dairy products.<sup>349</sup> The Commission went on to note that an EU-NZ FTA is expected to provide the necessary framework to effectively address these

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<sup>346</sup> Ministry of Foreign Affairs and Trade *EU-NZ Free Trade Agreement*, above n 302, at 2.

<sup>347</sup> For a full list of those product names which the EU is seeking recognition of and protection of as geographical indications in an EU-NZ FTA, see Ministry of Foreign Affairs and Trade “Consultation on EU-NZ free trade agreement” <<https://www.mfat.govt.nz/en/trade/free-trade-agreements/agreements-under-negotiation/eu-fta/consultation/>>.

<sup>348</sup> European Union “Proposal for the EU-New Zealand FTA”, above n 320, art X.34.1.

<sup>349</sup> European Commission *Impact Assessment*, above n 338, at 28.

issues. During scoping discussions both parties agreed that the provision of a broader framework for the recognition and protection of GIs should be aimed for during the course of negotiations.<sup>350</sup> However, any agreement on that framework would be subject to an overall satisfactory outcome for New Zealand.

In addition to the framework, a satisfactory outcome would also include the specific names that the EU has proposed for protection in New Zealand. A number of those proposed names will be deemed ‘sensitive’ by New Zealand producers, especially those pertaining to cheeses and dry-cured meats. Any protection of sensitive names must take into consideration the continuous and common use of those names by domestic producers, adequately balancing their interests against those of EU GI holders. Consequently, the issues that New Zealand would face in relation to the protection of GIs is whether New Zealand *should* adopt GI protections as advocated for by the EU and, if so, how would New Zealand ensure an appropriate balance is struck between upholding protection for those GIs and permitting limited and legitimate exceptions to their use.

(a) Extension of GI protection to agricultural products and foodstuffs

It is undeniably clear that to protect specific terms in the manner proposed by the EU would cause significant prejudice to how those terms are currently used in New Zealand. Conferring protection as proposed would prevent the outright use of those terms in the marketing of a product that falls within the given product class. Presently there are no exceptions in the EU’s proposed text for continuous use or generic terms. This means that producers would need to rebrand or rename their products so that they may still be marketed.

Of concern to New Zealand producers is the long-standing use of terms which have become familiar to New Zealanders as names for particular types of products.<sup>351</sup> Such names include, but are not limited to, Feta, Cheddar, Danbo, Parmesan, Gouda, Halloumi and Prosciutto. As a result, producers have invested in the development and maintenance of those names,<sup>352</sup> consequently establishing reputation in their particular brand. More generally, it has further been contented that given the global incidence of immigration and the importation of traditional practices as a result, the link between geographical location and name has been whittled away

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<sup>350</sup> Ministry of Foreign Affairs and Trade *EU-NZ Free Trade Agreement*, above n 302, at 2.

<sup>351</sup> Kimberly Crewther *Submission to the Ministry of Foreign Affairs and Trade on the Proposed New Zealand/European Union Free Trade Agreement* (Dairy Companies Association of New Zealand, February 2016) at 13.

<sup>352</sup> At 13.

and many names have now entered the common language as a generic name.<sup>353</sup> The name no longer denotes origin but rather indicates the style of product which falls within that name.<sup>354</sup> Opponents to GI expansion therefore emphasise both the time and expense incurred in rebranding products and the likelihood of consumer confusion arising from that rebranding.<sup>355</sup>

Conferring protection to specific names would not only affect New Zealand producers who market their products under those names but would also affect foreign producers who sell their products in New Zealand under those same names. The reason being that protection would be afforded against the use of those names *in New Zealand*, rather than against the use of those names *by New Zealand producers*. Presently, cheese marketed as Feta and produced in Denmark and Bulgaria may be sold in New Zealand, as Feta is not protected by New Zealand as a GI. Were New Zealand to protect Feta as a GI, the marketing of those products would no longer be permitted under that name. The implication is that either producers of these products would similarly need to rebrand or those products would simply be pulled off the New Zealand market to the detriment of consumers who may enjoy those particular products.

Conversely, the marketing of products produced in New Zealand under a protected name for the purpose of export would not require rebranding. In this situation, the product is not intended for the New Zealand market and would therefore not fall foul of any protection. With that being said, the rising trend of including GIs within trade agreements means that names once unprotected may be subsequently protected by a party in order to fulfil its trade obligations. Caution must therefore be exercised in ensuring that products exported under a name are in compliance with the importing country's international obligations. In this respect, increased global protection may lead to a change in business practice as it becomes more difficult to export certain products that do not conform to the specifications attached to a given name.

While the concerns raised by producers are legitimate, the detrimental effect of protecting the specific names proposed by the EU would in fact be limited to a handful of names. For all others, there should not be any such effect. This is because most names proposed by the EU for protection are specific to a particular place or region or consist of compound names. The implication is that many of those names for which protection is sought are not actually used in

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<sup>353</sup> Calboli, above n 81, at 198.

<sup>354</sup> Rachael Koelmeyer "Geographical Indications, European Trade and Indigenous Rights – A Fair Exchange?" (8 May 2019) Ellis Terry <<http://ellisterry.com/geographical-indications-european-trade-and-indigenous-rights-a-fair-exchange/>>.

<sup>355</sup> Calboli, above n 81, at 198.

the marketing of New Zealand products. With respect to wines, it has been acknowledged that GI protection may be less contentious than for other products in light of the Geographical Indications (Wine and Spirits) Registration Act.<sup>356</sup> Names which may be controversial have been identified as those registered under a single name, including ‘Sherry’, ‘Port’, ‘Chablis’ and the recognised grape varieties ‘Prosecco’ and ‘Montepulciano’.<sup>357</sup> Each of these names are included within the EU’s proposed list of wine GIs; a list which comprises 31 pages and hundreds of wine GIs.<sup>358</sup>

A similar situation exists for agricultural products and foodstuffs. For example, rather than seek protection for the name ‘Parmesan’, the EU has sought protection for ‘Grana Padano’ and ‘Parmigiano Reggiano’ instead.<sup>359</sup> This is despite the EU-held belief that the name Parmesan has not become a generic term.<sup>360</sup> Similarly, ‘Prosciutto’ has not been proposed for protection but rather ‘Prosciutto di Parma’ and ‘Prosciutto di San Daniele’ for Italy and ‘Dalmatinski pršut’, ‘Istarski pršut’ and ‘Krčki pršut’ for Croatia.<sup>361</sup> Names considered generic by New Zealand have also been proposed under their registered names, including ‘Camembert de Normandie’, ‘Brie de Meaux’, ‘West Country Farmhouse Cheddar cheese’ and ‘Gouda Holland’. Indeed, the compound name approach taken by the Netherlands in submitting for registration of Gouda and Edam cheeses in 2003 was welcomed as pragmatic by the Dairy Companies Association of New Zealand, as New Zealand Gouda may still be legitimately marketed in the EU as a result.<sup>362</sup>

Further, concerns were initially raised in relation to established international standards for commonly known cheeses under the Codex framework<sup>363</sup> and the possibility that some of those cheeses may be subsequently included for protection within an EU-NZ FTA.<sup>364</sup> The names included within Codex are what may be said to be the generic names for those where protection

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<sup>356</sup> New Zealand Wine “Submission on the Proposed Free Trade Agreement between New Zealand and the European Union” (3 March 2016) at 7.

<sup>357</sup> At 7.

<sup>358</sup> European Commission “Wines – Full List” (12 September 2018).

<sup>359</sup> European Commission “List of EU Geographical Indications (GIs) submitted within the framework of the negotiations of Free Trade Agreements with New Zealand – foodstuffs” (01 October 2018).

<sup>360</sup> Case C-132/05 *Commission of the European Communities v Federal Republic of Germany* [2008] ECR I-957 at [49] and [52]. Note that the Court found that the name ‘Parmesan’ must be regarded as an evocation of the PDO ‘Parmigiano Reggiano’ before going on to say that it is far from clear that the designation ‘Parmesan’ has become generic.

<sup>361</sup> European Commission, “List of EU Geographical Indications”, above n 359.

<sup>362</sup> Crewther, above n 351 at 14.

<sup>363</sup> Food and Agriculture Organization of the United Nations “Codex Alimentarius: International Food Standards”

<sup>364</sup> Crewther, above n 351.

is sought by the EU under their registered name. The names Brie, Camembert, Emmental, Mozzarella, Provolone, Edam, Gouda and Cheddar all have established global standards for their production under Codex and are all included within the EU's list of proposed foodstuffs under their registered names.

On the other hand, cheese names such as Danablu, Gruyère, Munster, Feta, Asiago, Fontina and Gorgonzola are included in the EU's proposed list for protection in an EU-NZ FTA and do not have established international standards for their production. This implies that while common names may not be prevented from use in the marketing of such products worldwide, names that are not included on Codex may not be said to be considered common and may therefore receive protection to prevent the genericisation of their names. Interestingly, Parmesan is not included on Codex and therefore its status as a generic name remains contested. What is noteworthy is the inclusion on Codex of Danbo and Havarti cheeses, yet both names were subsequently submitted for registration by Denmark on the EU Commission's Database of Origin and Registration, where Danbo became registered as a PGI in 2017.<sup>365</sup> Neither name is included on the EU's proposed list for protection. This suggests that common names may be reclaimed by the EU. Whether or not international protection will later be sought remains to be seen.

While the protection of GIs would come at a cost to certain product names, it also presents an opportunity for New Zealand to promote its own unique products and seek international protection for associated product names. As an example, the opportunity to protect New Zealand wines under the Geographical Indications (Wine and Spirits) Registration Act was welcomed by the wine industry which emphasised the registration system as "providing a secure and solid platform for New Zealand wine producers to promote our wines and regions in international markets".<sup>366</sup> For the wine industry in particular, GI protection acted as a means to protect and promote their products in the EU market due to the EU's highly complex and prescriptive regulatory system.<sup>367</sup> This was compounded by the fact that in order to receive protection for New Zealand names in the EU the product must first be formally registered in

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<sup>365</sup> European Commission: Agriculture and Rural Development "Database of Origin and Registration" (DOOR).

<sup>366</sup> New Zealand Wine "Geographical Indications – Protecting the places that make our wine famous" <<https://www.nzwine.com/en/our-regions/geographical-indications/>>.

<sup>367</sup> Ministry of Business, Innovation and Employment "Geographical Indications (Wines and Spirits) Registration Amendment Bill: Initial Briefing to the Primary Production Select Committee" (5 May 2016) at 12 and 18.

its place of origin.<sup>368</sup> For this reason, GI protection for wines was deemed necessary to promoting New Zealand wines on the international market.

Since coming into force, a number of New Zealand wine associations and societies have registered GIs for their demarcated region, including Central Otago, Gladstone, Hawke's Bay, Marlborough, Waiheke Island and Waipara Valley.<sup>369</sup> Others are yet to register their interest or announce an intention to do so. For example, the Hawke's Bay Winegrowers Association Gimblett Gravels has established a world-renowned reputation for their product which places significant emphasis on the unique qualities provided by the gravelly soils on which their Member's products are grown.<sup>370</sup> Presently it is protected in New Zealand by a collective mark but would qualify for GI protection should it wish to do so.<sup>371</sup> While GI protection would undoubtedly confer benefits to that brand, it may be that the name is sufficiently protected on international markets under a pre-existing trade mark. Given EU domestic and multilateral rules on the rights attached to pre-existing trade marks, it may be that protection under a GI is considered unnecessary.

The opportunity presented by GI protection is also applicable to agricultural products and foodstuffs. New Zealand has an abundance of unique and innovative food products which would benefit from GI protection by preventing not only their misuse or misappropriation but also from diminishing in economic value. Such products include Kapiti and Morrinsville cheeses, Bluff Oysters, Nelson Sauvignon hops and Manuka honey. Of those, Kapiti, Bluff Oysters and Manuka honey are protected by registered trade marks.<sup>372</sup> However, it also gives producers of products which may be affected by any GI protection the opportunity to rebrand and diversify their products. Irrespective of the cost, this would enable producers to distinguish their products from others and create a reputation in a new market unique to them.

Were New Zealand agricultural products and foodstuffs to benefit from GI protection then their transition onto international markets would be much more streamlined and less bureaucratic. It would enable producers to set common standards for the production of a product and exclude

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<sup>368</sup> At 19.

<sup>369</sup> See Intellectual Property Office of New Zealand, Geographical Indications Register <<https://www.iponz.govt.nz/about-ip/geographical-indications/register/>>.

<sup>370</sup> Gimblett Gravels "Our Story" <<https://gimblettgravels.com/?age-verified=e3d07398fd>>.

<sup>371</sup> Intellectual Property Office of New Zealand, Trade Mark Register, IP Number 772672.

<sup>372</sup> Intellectual Property Office of New Zealand, Trade Mark Register, IP Numbers 786321 (Kapiti), 659808 (Bluff Oysters) and 1075383 (Manuka honey – UMF). Note that Nelson Sauvignon hops was initially submitted for registration on 14 November 2016 but has been subsequently abandoned. Intellectual Property Office of New Zealand, Trade Mark Register, IP Number 1055117.



from the use of their GI all other products which do not conform to those set standards, including standards linking geographical origin to quality. This would assist in establishing a reputation which is built upon the quality delivered by products marketed under that GI.

A prime example of a product which would benefit from this opportunity is Manuka honey. Until recently, Manuka honey was produced and sold under multiple quality standards, such as UMF 10+, MGO 250, MGS 16+ and OMA 16+. <sup>373</sup> Not only were these standards confusing to a consumer but there was also no recognised testing regime to verify the health claims touted by producers of ‘active’ Manuka honey. <sup>374</sup> Unsurprisingly, Manuka honey has been subject to global counterfeiting and mislabelling, in addition to international competition. <sup>375</sup> It has recently been recognised that in order for New Zealand to maintain the premium position of Manuka honey in overseas markets, confidence in the authenticity and integrity of the product is essential. <sup>376</sup>

Protection for Manuka honey is on the rise. The Ministry for Primary Industries in December 2017 approved a “robust and scientific definition” to determine the authenticity of Manuka honey which centres upon a combination of five attributes. <sup>377</sup> This approved definition came on the back of a decision by the United Kingdom Trade Mark Registry to uphold the name “Manuka” as a Maori word that is accepted as the common word for the specific plant variety of *Leptospermum Scoparium*, grown in New Zealand, thereby accepting Manuka honey as a certification mark. <sup>378</sup> Soon after a certification mark applied for by the Manuka Honey Appellation Society Incorporated in August 2015 was approved by IPONZ but is yet to be registered due to opposition by Australian competitors and indigenous stakeholders. <sup>379</sup>

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<sup>373</sup> Coriolis *Investment Opportunities in the New Zealand Honey industry* (Part of the Food and Beveridge Project, May 2012) at 48.

<sup>374</sup> At 46.

<sup>375</sup> Note that Australia is a significant producer of “Active Jelly Bush Honey” which is made from the nectar of the tree *Leptospermum polygalifolium*; a close relative of the tree *Leptospermum scoparium*, commonly known as Mānuka. Jelly Bush Honey has been marketed as “Australia’s Manuka”. See Coriolis, above n 373, at 54.

<sup>376</sup> Ministry for Primary Industries “Mānuka honey” <<https://www.mpi.govt.nz/growing-and-harvesting/honey-and-bees/manuka-honey/>>.

<sup>377</sup> See Ministry for Primary Industries “Mānuka Honey Science Definition” <<https://www.mpi.govt.nz/dmsdocument/17374-manuka-honey-science-definition-infographic>>.

<sup>378</sup> See BusinessDesk “MPI unveils official manuka honey definition” (12 December 2017) The National Business Review <<https://www.nbr.co.nz/article/mpi-unveils-official-manuka-honey-definition-211066>> and Scoop “Landmark UK decision major step in protecting Mānuka honey” (12 December 2017) <<http://www.scoop.co.nz/stories/BU1712/S00357/landmark-uk-decision-major-step-in-protecting-manuka-honey.htm>>.

<sup>379</sup> Intellectual Property Office of New Zealand, Trade Mark Register, IP Number 1025914.

Notwithstanding potential protection under a certification mark, Manuka honey would benefit from greater protection under a GI.

While it is clear that the EU's draft IP chapter offers an opportunity for New Zealand products to branch out and benefit from EU-style GI protection, it is also clear that such protection would be detrimental to other producers and their products. An appropriate balance to GI protection must therefore be struck between the economic benefits and costs of protecting GIs, to ensure sufficient protection against unfair competition and misappropriation without imposing undue restrictions which would undermine the functioning of a competitive market.<sup>380</sup>

(b) Striking an appropriate balance

Concerns raised by producers primarily focus on the long-standing or continuous use of terms which have become familiar to New Zealanders as names for particular types of products. Such use came about through immigration and the importation of traditional ways of life and have since been developed and maintained as commercial names for those products. Protection as advocated by the EU would have a significant detrimental impact upon industries that have used those names in good faith for many years. Given the economic costs in protecting specific GIs proposed by the EU, it is highly conceivable that a satisfactory outcome for New Zealand will be conditional upon the inclusion of an exception for continuous use within an EU-NZ FTA.

No such exception was included in the EU's draft IP chapter. It may be inferred that an exception was omitted as exceptions for continuous use are not permitted within its domestic law, other than where there is a pre-existing trade mark. Irrespective of this omission, continuous use is protected under art 24.4 of the TRIPS Agreement in relation to wines and spirits that have been used in a continuous manner for at least ten years preceding that Agreement. Unless the Parties expressly provide to the contrary, this obligation should remain enforceable as an international obligation irrespective of whether a provision is included that would protect continuous use.

With that being said, a multi-layered exception for continuous use was incorporated within CETA in order to take into account the domestic situation of Canada. That exception applies specifically to a limited number of GIs and to varying degrees. At its broadest, art 20.21.2 provides that those products listed in annex 20-A and identified with one asterisk may continue

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<sup>380</sup> Calboli and Gervais, above n 85.

to be used in Canada by “any persons, including their successors and assignees, who made commercial use of those indications with regard to products in the class of ‘cheeses’ preceding the date of 18 October 2013”. Those products identified with one asterisk are Feta, Munster, Asiago, Fontina and Gorgonzola. These GIs may be considered as contested between the parties, where their use under art 20.21.1 is only permitted in combination with accompanying expressions and the inclusion of a legible and visible indication of their true geographical origin. Due to their contested nature, a broader exception is maintained for continuous use.

Further continuous use exceptions are provided for products listed in annex 20-A and identified with either two or three asterisks and apply where there has been continuous use for at least five or ten years respectively from the above-stated date.<sup>381</sup> Where there has been commercial use of the specified products for less than the duration required to constitute continuous use, a transitional period of five years shall apply, provided the commercial use occurred prior to the above-stated date. In total, only eight GIs are subject to the above continuous use provisions in CETA.

The inclusion of continuous use exceptions within CETA indicates that the EU could be willing to introduce similar provisions into an EU-NZ FTA. Given the similar historical positions of New Zealand and Canada with respect to immigration and the importation of traditional practices, it may be assumed that similar treatment could be expected. That said, the respective negotiating power of Canada and the market situation for products where continuous use was sought would be different to that of New Zealand. This could also be the case in relation to the specific products for which continuous use exceptions are sought. New Zealand may be able to use the inclusion of continuous use exceptions as a bargaining tool for protecting EU GIs. The extent to which those provisions may be included and what terms may fall within that exception would be a matter for the Parties to determine in the course of negotiations, having due regard to the actual position of New Zealand.

It is important to note that a provision has been included within the draft IP chapter that would protect pre-existing trade marks that would otherwise fall foul of GI protection. The problem for New Zealand is that a search on the IPONZ trade mark register indicates that while the brand name of products which are marketed under names where continuous use may apply are registered, the names of those products themselves are not registered. So, for example, Bouton D’or, Kapiti and Perfect Italiano are registered but the types of cheeses that may be marketed

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<sup>381</sup> CETA, above n 5, art 20.21.3 – 4.

under those brands (ie Feta, Parmesan, and Gruyère) are not. On this basis it may be said that the inclusion of continuous use provisions is crucial for the ability of such brands to continue marketing those cheeses as they may not fall back on the provision regarding pre-existing trade marks.

Operating in tandem with continuous use is the belief that many of those names used by producers over the years have fallen into the common language as generic names. Helpful guidance for determining what is or is not generic may be those names included on Codex as discussed above, given the contribution of the EU and its Member States to the development of the standards therein. Of those names included within the EU's proposed list of foodstuffs GIs, none are included within Codex. This does not mean that all the GIs proposed by the EU are considered non-generic to New Zealand. In fact, a number of those terms are considered contentious between the EU and New Zealand.

It has been reported that objections have been made with respect to 29 of the 59 dairy products that the EU has sought protection for.<sup>382</sup> Public submissions pertaining to the EU's proposed lists and calling for nominations of any New Zealand terms to be put forward for consideration of EU protection opened in late 2018 and closed on the 19<sup>th</sup> of March 2019. Submissions made during that consultation period have not yet been publicly released. It is not the place of this author to speculate which terms may have been opposed within those submissions. That said, earlier submissions made to MFAT in relation to the EU-NZ FTA make clear that the terms 'Feta', 'Parmesan' and 'Gruyère' are considered common within New Zealand and may therefore be opposed as either generic terms or terms protected by continuous use.<sup>383</sup>

No specific provision is included within the draft IP chapter for exceptions relating to generic use of a term.<sup>384</sup> This is inconsistent with both CETA and EU domestic law, both of which provide limited exceptions for generic use. As discussed above, use of a generic term is either expressly or impliedly permitted under EU law and includes use where the generic term is part of a name that is protected under a GI. Similarly, art 20.21.7 of CETA protects the right to use either a translation of a GI or a term that is contained within a GI, where that term is customary

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<sup>382</sup> Nigel Stirling "Dairy industry tells EU 'hard cheese'" (03 April 2019) Farmers Weekly <<https://farmersweekly.co.nz/#>>.

<sup>383</sup> Crewther, above n 383.

<sup>384</sup> Note that Section B of Annex [XX]-A lists elements for registration and control of geographical indications, including provisions concerning the registration or refusal of registration of terms customary in common language as the common name for goods. Note that these elements go towards procedure and not exceptions to protection.

in common language as the common name for a product. In the former, use of the translated term ‘Parmesan’ would be considered a permissible exception as a term deemed customary in the common language of New Zealand, as the GI ‘Parmigiano Reggiano’ is included within the EU’s proposed list of foodstuffs GIs. Whereas use of the term ‘Camembert’ would be considered a permissible exception in the latter instance as the common name for the GI ‘Camembert de Normandie’, which is also included within the EU’s proposed list. While Camembert is a name included on Codex, concerns have been expressed that the EU may be reclaiming generic names, given the recent registration of Danbo and the recent submission for registration of Havarti.<sup>385</sup> Inclusion of a provision protecting generic use in relation to translations and partial use of GI would therefore allay concerns and ensure certainty for producers who invested in the development and maintenance of those terms. Exceptions for generic use may be utilised as a bargaining tool should New Zealand agree to afford protection to EU GIs as advocated by the EU.

It has been contended that a balanced system should provide allowances for generic producers who already produce in markets where GI protection has only recently been introduced or where protection is not yet afforded.<sup>386</sup> Allowances would include exceptions for both continuous and generic use. Another solution would be to remove the exclusion of accompanying terms such as ‘kind’, ‘type’, ‘style’, ‘imitation’ or the like, provided that the use of such terms does not mislead consumers as to the place of origin.<sup>387</sup> While this approach would be strongly opposed by the EU, it may assist in striking the balance between combatting misappropriation and ensuring a competitive market. At the same time, such a compromise may contribute to a wider global embracement of GI protection.<sup>388</sup>

Given the priority placed by the EU on GI protection and the entrenched protection of terms against use, including use with accompanying terms, it is highly unlikely that such a solution would be considered let alone adopted by the EU. That said, CETA permitted continued use of the terms ‘Feta’, ‘Munster’, ‘Asiago’, ‘Fontina’ and ‘Gorgonzola’ by Canada without accompanying terms where commercial use had occurred prior to 18 October 2013. It also permitted new use of the same terms *with* accompanying terms.<sup>389</sup> This suggests that while the

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<sup>385</sup> Peter Burke “Cheesed off with EU” (01 November 2017) Dairy News

<<https://www.ruralnewsgroup.co.nz/dairy-news/dairy-general-news/cheesed-off-with-eu>>.

<sup>386</sup> Calboli and Gervais, above n 85.

<sup>387</sup> Calboli and Gervais, above n 85.

<sup>388</sup> Calboli and Gervais, above n 85.

<sup>389</sup> CETA, above n 5, art 20.21.1.

EU would not be prepared to accept use with accompanying terms for all GIs, it may accept such use in limited circumstances. An appropriate balance in an EU-NZ FTA could see such use permitted in the event that contentious terms are not excluded by the Parties in the course of their negotiations.

In addition to issues surrounding the level of protection sought for specific terms, outstanding issues relating to regulatory aspects remain which create further barriers to legitimate competition. With respect to EU classification of a product as a PGI, at least only one of the production steps must take place in the defined geographical area. This is opposed to a PDO where all the production steps must take place in the defined geographical area. It has been contended that GI protection should only be granted to those producers whose products are either grown or are manufactured in their entirety in that geographical area.<sup>390</sup> Without a strong linkage between product and location, the GI would effectively operate as a disguised subsidy for local producers against outside competition and would be misleading as to product origin.<sup>391</sup> A strong linkage would serve to increase rather than stifle competition as a GI merely prevents competitors from using “the same nomenclature”, but does not prevent them from producing the same type of product and marketing it under a different name.<sup>392</sup> Thus, GI protection could result in increased competition through product differentiation and innovation.<sup>393</sup> While regulatory aspects such as GI classification are outside the scope of this thesis, it is worth noting as a consideration for New Zealand in determining the extent to which GI protection may be afforded or a term may be registered within New Zealand.

Finally, if New Zealand were to afford protection to agricultural and foodstuffs GIs, it must ensure that the mode of protection is appropriate for New Zealand. Whether this may be via a registration scheme similar to that implemented for wines and spirits under the Geographical Indications (Wine and Spirits) Registration Act or through either a certification or collective mark is for New Zealand to determine, having due regard to that which will minimise the harm caused as a result of GI protection. While a GI registration scheme would confer the strongest protection to both EU and New Zealand products it would cause the most harm to New Zealand producers whose products are currently marketed under names where protection is sought. Whereas protection under either a certification or collective mark would run the risk of

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<sup>390</sup> Calboli and Gervais, above n 85.

<sup>391</sup> Calboli and Gervais, above n 85.

<sup>392</sup> Calboli and Gervais, above n 85.

<sup>393</sup> Calboli and Gervais, above n 85.

weakening protection, with particular regard to accompanying terms. In addition, neither mark requires a link between geographical origin and quality. With that said, New Zealand producers have not generally organised themselves under a consortium or organisation that would allow for protection under a collective mark. It may therefore be more practicable and least harmful to confer protection by way of a certification mark. At the time of writing, protection by way of a certification mark has been disclosed as the most likely candidate for protection were protection to be granted.<sup>394</sup> Whatever the outcome, it is for the Parties to determine during the course of negotiations.

*C Reconciliation of Obligations under Existing Trade Agreements: Trade marks and the CPTPP*

In protecting GIs as advocated by the EU, New Zealand would be committing itself to applying two distinct systems for the protection of distinctive signs. The first being the protection of signs as GIs under an EU-NZ FTA and the second being the protection of signs as trade marks under the CPTPP. It does not necessarily follow that this imposes conflicting obligations on New Zealand. The primary consideration when granting protection to either a GI or a trade mark relates to timing and whether a pre-existing GI or trade mark already exists. Where one does exist, neither agreement requires the invalidation of the other form of protection but rather permits their co-existence.<sup>395</sup> In the event of a conflict between its obligations, New Zealand law would “favour the first-filed application for either type of right”.<sup>396</sup>

The CPTPP, however, goes beyond that required under the EU’s draft IP chapter by imposing obligations on the parties to that Agreement with respect to applications or petitions for GI protection or recognition. These obligations apply in respect of applications made where GI protection is granted under national law and also where GI protection is conferred pursuant to an international agreement. With respect to the latter, the party must ensure that all applications for GI protection are published and subject to objection procedures, as well as provide for cancellation or refusal of GI protection.<sup>397</sup> In addition, the party must detail online the terms that protection is sought for and any transliterations or components of a multi-component term,

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<sup>394</sup> Martin Harvey, Lead Negotiator EU-NZ FTA “EU-NZ Free Trade Agreement – Chief Negotiator’s Talk” (Public Session, Wellington, 15 May 2019).

<sup>395</sup> See TPP Agreement, above n 7, art 18.20 and Proposal for the EU-New Zealand FTA, above n 320, art X.36.6.

<sup>396</sup> James Ting-Edwards, Melanie Johnson, Judge David Harvey, Debbie Monahan, Kate McHaffie and Jo Shaw *TPPA: Intellectual Property and Information Technology* (Trans-Pacific Partnership Agreement New Zealand Expert Paper Series, Expert Paper #7, February 2016) at 16.

<sup>397</sup> TPP Agreement, above n 7, art 18.36.1.

and provide reasonable time for a person to oppose the protection of any term.<sup>398</sup> The purpose of these objection procedures is to enable a party to the CPTPP to raise an objection against the protection of a term in another party where they have legitimate grounds to oppose that protection. Grounds for opposition and cancellation are set down in art 18.32.1 of the TPP Agreement, being where the GI is likely to cause confusion with a pre-existing trade mark or a trade mark that is held in good faith and where the GI is a customary or generic term in that party.

The CPTPP requires parties to that Agreement to provide a reasonable opportunity for other parties to that Agreement to object to an application for GI protection pursuant to another international agreement. Here, the focus is on consultation with other CPTPP parties in order for a party to raise a legitimate objection to an application for protection of any given term. There is, however, no requirement for the party to refuse protection to that GI merely because another party has raised an objection. Rather, the objection must be supported by one of the three grounds for opposition in order for protection to be denied. Provided that the consultation obligations have been complied with prior to acceptance and registration of a GI, the party has acted consistent with its obligations under the CPTPP. Were that party to grant protection for that GI prior to consulting, however, there could be infringement as protection may have been conferred in contravention of a party's legitimate objection. A prudent approach that would minimise the risk of infringing a trade agreement would therefore be to consult prior to any decision on the conferral of GI protection. This approach was taken by MFAT with respect to the EU-NZ FTA, by calling for public submissions on the EU's proposed list of GIs, thereby providing other CPTPP parties the opportunity to raise objections.

The grounds for opposition or cancellation firstly suggests that there is a form of pre-existing right to the use of that term *in the territory of the party*. The emphasis here is that the right is not pre-existing for the party putting forward the objection, but the party for where GI protection is sought. This would operate to void provisions permitting the co-existence of trade marks and GIs but would comply with the general approach which favours the first-filed application.

It is not enough to show that there is a pre-existing right. It must also be shown that where that pre-existing right relates to a trade mark, whether registered or subject to pre-existing good faith, the GI *is likely to cause confusion* with that trade mark. Provided that the GI makes clear

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<sup>398</sup> TPP Agreement, above n 7, art 18.36.1(b) and (c).



the true origin of the product or displays images or logos which operate to distinguish the products, it cannot be said that confusion is caused. The focus on elements relating to consumer protection assists in circumventing the grounds relating to pre-existing trade marks.

Where the pre-existing right does not relate to a trade mark, it must be shown that the GI “is a term *customary in the common language as the common name for the relevant good*”.<sup>399</sup> As is made clear in art 18.33 of the TPP Agreement, it is the party in which protection is sought that has the authority to “take into account how consumers understand the term in the territory of that Party” in determining genericity. There is no obligation on the party to base their decision on consumer understanding, only that consumers’ understanding of that term is to be taken into account. This imposes a low threshold as it requires little more than turning the mind to how a term is perceived by consumers. Ultimately, other factors may take precedence. That said, a term is said to be generic when it is understood as the common name. If consumers do not understand it to be the common name then the argument putting forward the term as generic is drastically weakened. In this respect, consumer understanding ought to be taken into account in *any* determination of genericity. On this basis, it is arguable that this ground of opposition or cancellation has little significant effect, or imposes nothing additional to what would already be considered when making a decision regarding genericity.

On the other hand, that ground of opposition could operate as a valuable tool to avoid protecting a given GI term where that term is considered generic by the party in which protection is sought. Provided an objection is made on this ground, a party may uphold the objection and fall back on their international obligations in refusing to confer protection to that contested term. In this respect, the provision could be just as beneficial as it is restrictive on the free will of a party. For example, protection for the term ‘Feta’ within an EU-NZ FTA may be opposed by a CPTPP party on the ground that it is a generic term within New Zealand. This would be welcomed by producers of Feta as, were that objection to be deemed valid, New Zealand would be bound under the CPTPP to refuse protection to that term.

One final note to make is that the definition of a geographical indication within the TPP Agreement provides that it means “an indication that identifies a good as originating in the territory of a Party ...”.<sup>400</sup> It has been pointed out that as a GI is defined in terms of a ‘Party’s’

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<sup>399</sup> TPP Agreement, above n 7, art 18.32.1(c). Emphasis added.

<sup>400</sup> TPP Agreement, above n 7, art 18.1.1. Emphasis added.

territory, it excludes from the definition GIs of a party who is not a Party to the CPTPP.<sup>401</sup> On this basis it would appear that the provisions relating to the relationship between trade marks and GIs do not apply to non-party GIs. However this interpretation fails to consider that art 18.36.1 of the TPP Agreement expressly applies to GIs *pursuant to an international agreement* and contemplates that such agreements will be entered into with non-CPTPP parties. It is therefore incorrect to assume that non-party GIs may not be subject to the provisions within the TPP Agreement in relation to opposition procedures.

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<sup>401</sup> Ting-Edwards and others, above n 396, at 16.

## *VI Conclusion*

### *A Introduction*

The purpose of this thesis was to identify those TRIPS-plus protections relating to pharmaceuticals and GIs that may be included within an EU-NZ FTA and the implications arising from any implementation of those protections in New Zealand domestic law. A comparative interpretative analysis of TRIPS-plus protections in recent FTAs identified three forms of protection which would pose a significant challenge to the Parties during the course of their negotiations. It was determined that implementation of those protections would come at a cost to New Zealand, however, it is possible to minimise the harm or take advantage of the opportunities that are simultaneously offered. It was further determined that despite conflicting obligations under its trade agreements, New Zealand could protect distinctive signs as GIs without breaching its obligations.

### *B Summary of Findings*

A comparative interpretative analysis of TRIPS-plus protections identified a number of differences between the Parties in respect of protection for pharmaceuticals. Of those, differences relating to patent term extension and data and market exclusivity were identified as posing the most significant challenge or difficulties for the Parties during the course of negotiations.

This thesis made it clear that the implementation of either patent term extension or extended data and market exclusivity provisions would be detrimental to New Zealand. To implement a patent term extension scheme would have the consequence of delaying the entry of generic pharmaceutical products onto the New Zealand market. As a high consumer of IP, New Zealand has a strong interest in ensuring rapid entry of generic pharmaceutical products onto the market so that consumers have access to affordable medicines. Implementation of a patent term extension scheme would have the consequence of hindering access to life-saving medicines. A similar consequence arises from the implementation of extended data exclusivity provisions as such provisions prevent generic pharmaceutical companies from relying on the originator's data in obtaining marketing authorisation. To implement a period of market exclusivity in addition to data exclusivity would further delay entry of generics onto the market.

Given the high cost of originator pharmaceutical products and New Zealand's reliance on generics, there is no benefit to New Zealand in implementing either forms of protection.

That said, it is possible to minimise the risk of harm. The patent term extension scheme of the EU takes into account the entire period between the filing of the patent application and the granting of marketing authorisation; the aim being to compensate for the reduction in effective patent term. However, this approach takes into account all delays, including those that are not directly attributable to the approval or authorisation processes. Whereas in fulfilling its TPP obligations, New Zealand passed legislation (not in force) that would distinguish the two processes and remove from consideration delays not directly attributable to those processes. While it is arguable that due regard should be had for the clinical testing phase, as testing is required in order to obtain marketing authorisation, a TPP-style scheme would provide the least harm to consumers whilst also compensating for the loss that has actually occurred. Given the efficiency of those regulatory bodies responsible for the approval and authorisation processes, it is expected that few delays would occur.

A fairer method that is consistent with the EU's purpose for granting *sui generis* protection would be to take into consideration delays in the testing phase, minus any time which the applicant failed to act with due diligence. Such an approach may result in the granting of more extensions but would go towards reconciling the interests of both Parties.

It is also possible to minimise, to an extent, the risk of harm in implementing data or market exclusivity provisions. Were New Zealand to implement such provisions, the outcome with the least impact would be to simply lock-in existing policies on data protection. This would prevent New Zealand from lowering the current levels of protection but would not entail the implementation of any additional protection. A similar approach was taken within CETA; however, it did require Canada to implement a period of market exclusivity which it previously did not provide.

Should New Zealand be required to implement provisions additional to the present level of protection, New Zealand's current laws offer a degree of protection to lessen the impact. Given that the minimum patent term is 20 years and efficient regulatory procedures permit the quick entry of products onto the market, it is very unlikely that a patent term will expire before the period of data exclusivity expires. A generic company may not market its product, even if it has obtained marketing authorisation, until the patent term expires, without running the risk of infringement proceedings. Even were New Zealand to implement an extended period of data

exclusivity or enact a period of market exclusivity, it is unlikely that there will be a significant effect. The situation could be different with respect to biologics, however, the complexity and cost involved in producing biosimilars provide strong barriers to market entry as it is. Furthermore, New Zealand currently prohibits from obtaining data protection any data submitted for second uses of a known substance. Given that most new pharmaceutical products are developed using known substances, many will not qualify for data protection let alone protection for an extended period of time. It would be in New Zealand's interests for the current interpretation of 'innovative medicine' to be retained.

A comparative interpretative analysis of TRIPS-plus protections also identified a number of differences between the Parties relating to GIs. Presenting the most significant challenge or difficulties for the Parties was additional protection for specified terms. New Zealand also has obligations arising from the CPTPP which could conflict with any protection of GIs, unless those conflicting obligations can be reconciled.

This thesis made it clear that to protect GIs as advocated by the EU would come at a cost to agricultural producers who have invested time and money into the development and maintenance of terms familiar for certain types of products. That said, the potential harm is minimised by the fact that many of the terms where protection is sought are not used in New Zealand and, where they are, they are registered under compound names. Although the EU has not proposed any exceptions, exceptions are provided for within EU law and within CETA, indicating that New Zealand could negotiate the inclusion of exceptions for continuous use and generic terms. This would further minimise the impact of protecting GIs by limiting the extent to which rebranding would be necessary.

The protection of distinctive signs by GIs was also identified as representing an opportunity for New Zealand producers to diversify and create a reputation in a new market unique to them. New Zealand has an abundance of unique and innovate food products which would benefit from GI protection, given its focus on preventing the dilution in economic value through misuse and misappropriation. Having common standards linking geographical origin to quality would assist in establishing a reputation which is built upon the quality delivered by products marketed under that GI, to the benefit of New Zealand producers.

That said, New Zealand is bound to obligations under the CPTPP which seek to roll-back GI protection, limiting the global expansion of GIs. With respect to the entry into trade agreements with non-CPTPP Parties, New Zealand is bound to provide a reasonable opportunity for

interested parties to raise objections to any proposed GI protection. Provided an objection satisfies the grounds for objection, protection must be either refused or cancelled. However, the grounds for objection contain elements of consumer protection which seek to ensure consumers are not misled. Provided the GI is clearly distinguished from an existing trade mark so that confusion cannot occur, the GI may be protected. A further ground requires Parties to take into account consumer understanding of common terms. However, there is no obligation to base a decision regarding genericity on a consumers' understanding, although in practice it would be difficult to say a term is or is not generic if consumers do not hold the same opinion. On this basis, the conflicting obligations may be reconciled.

From another perspective, the CPTPP obligations could be utilised to avoid granting protection for a term, in particular where the genericity of a term is contested between New Zealand and the non-CPTPP party. In this respect, the obligations may in fact be beneficial to New Zealand.

Overall, any implementation of TRIPS-plus protections relating to pharmaceuticals and GIs within an EU-NZ FTA would come at a cost to New Zealand. However, outcomes are possible that would see the risk of harm minimised or reduced, and in fact may confer opportunities that New Zealand could embrace with respect to domestic products. A satisfactory outcome is achievable provided the Parties recognise and respect that each has the right to calibrate its laws to fit its specific needs and that any agreement must be mutually beneficial.

### *C Limitations*

This thesis has not been without its limitations. First, the scope of this thesis permitted the examination of only two trade agreements – one agreement concluded by each Party. This invokes a question regarding reliability, given that the premise of the thesis is based upon ideas of path dependency. For this reason, a second comparative interpretative analysis was conducted in order to assess the Parties' domestic laws. This provided a baseline to assess the difference between a Party's actual position and its negotiated position.

Second, it is expected that a comparison of trade agreements ought to produce divergent results as those agreements are a negotiated outcome. Every party to an agreement will have different interests, and the agreement will be reflective of those differences. It is therefore not possible to definitively conclude on an outcome but be limited to inferences.

Third, this thesis focused on TRIPs-plus protections. However, the CPTPP did not contain TRIPs-plus protections with respect to GIs, therefore a comparison between those protections was not possible.

Finally, this thesis focused on doctrinal legal analysis, therefore issues surrounding the economic and social impacts of implementing TRIPs-plus protections were not addressed in depth. This would have been beneficial to provide a comprehensive overview of the implications for New Zealand.

#### *D Future Research*

There is much scope for future research on the sufficiency of existing New Zealand law to adequately protect a GI. The scope of this thesis permitted the researcher to merely scratch the surface on this topic. While it is clear that the legal mechanisms addressing misuse and reputational damage only grant redress for one element of GI protection, there is the possibility that trade mark laws may provide sufficient protection. If not, then there is scope for future research to determine how we may amend existing laws to adequately protect GIs without necessitating the establishment of a GI register for agricultural products and foodstuffs.

A further area for research would provide an in-depth analysis of New Zealand's conflicting obligations under the CPTPP and any decision to confer GI protection. Such research may comprehensively address the grounds for opposition and the implications this has for New Zealand's obligations under the TRIPs Agreement, to protect pre-existing rights.

Two further questions arise out of interest but were outside the scope of this thesis. The first relates to the relationship between data exclusivity and compulsory licencing. Research in this area would be beneficial to understand how to reconcile conflicting obligations, to protect originator data whilst simultaneously authorising for market entry a product manufactured under a compulsory licence. The second relates to second use patents and infringement, where there is uncertainty surrounding the type of use that may or may not be deemed patentable. Given the tendency for New Zealand courts to follow international developments, research on developments in this area would contribute to understanding the possible direction New Zealand may take on this matter.

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